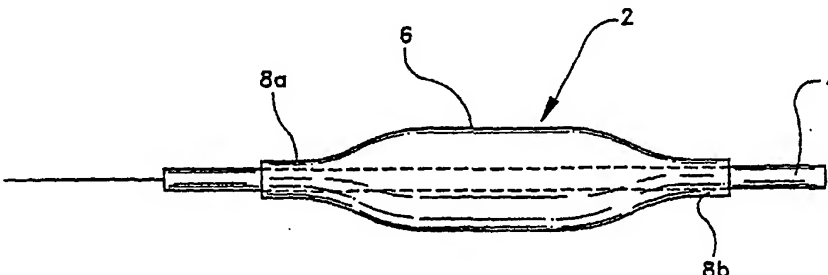


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| (54) Title: DILATATION BALLOONS CONTAINING POLYESTERETHERAMIDE COPOLYMER  |  |  |  |
|   |  |  |  |
| (57) Abstract   |  |  |  |
| Disclosed is a dilatation balloon having a single layer containing polyesteretheramide copolymer. The dilatation balloon may also contain polyamide and/or additional polymers, and may contain substantially no polyetheramide having substantially no ester linkages.   |  |  |  |

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DILATATION BALLOONS CONTAINING  
POLYESTERETHERAMIDE COPOLYMER

Background of the Invention

The present invention is generally directed to  
5 dilatation balloons containing polyesteretheramide  
copolymer.

The use of balloon catheters for coronary  
angioplasty is known in the art. In an angioplasty  
procedure, a partially occluded blood vessel, i.e., one  
10 containing a stenosis, is treated by the use of an  
expanding balloon member which presses the stenosis back  
against the vessel wall. Typically, the expander member  
or balloon is carried on the distal end of a dilatation  
catheter which is routed through the vascular system to a  
15 location within, for example, a coronary artery  
containing a stenotic lesion. Following placement of the  
expander member across the lesion as desired, fluid is  
introduced into the proximal end of the catheter to  
inflate the expander member to a relatively high  
20 pressure, thereby restoring patency to the vessel.  
Coronary angioplasty procedures and angioplasty devices  
are described in detail in Vliestra et al., "Coronary  
Balloon Angioplasty," Blackwell Scientific Publications  
(1994).

25 Medical balloons that are known in the art are  
disclosed in the following documents: U.S. Patent Nos.  
4 964 853 and 4 994 032 to Sugiyama et al; U.S. Patents  
No. 4 906 244, 5 108 415, 5 156 612, 5 236 659, and  
5 304 197, to Pinchuk et al; U.S. Patent Nos. 5 226 880  
30 and 5 334 148 to Martin; U.S. Patent No. 5 250 069 to

Nobuyoshi et al; U.S. Patent No. 5,328,468 to Kaneko et al.; European Patent Application No. 0 566 755; and Japanese laid-open patent application No. 58-188463. (All documents cited herein, including the foregoing, are incorporated herein in their entireties for all purposes.)

It is an object of the present invention to provide a balloon for an angioplasty device which is made, at least in part, of polyesteretheramide copolymer.

Other objects and advantages of the invention will become apparent to those skilled in the art through familiarization with the specification and claims herein.

#### Summary of the Invention

In sum, the present invention relates to a balloon for an angioplasty device having a single polymeric layer. The layer may have from about 20 to about 100 weight percent polyesteretheramide copolymer and from about 0 to about 80 weight percent polyamide. The layer contains substantially no polyetheramide having substantially no ester linkages. The polyesteretheramide copolymer may be a block or random copolymer. The polyesteretheramide copolymer may have a hardness of from about 45 Shore D to about 78 Shore D, preferably from about 55 Shore D to about 75 Shore D, and more preferably from about 63 to about 72 Shore D. Even more preferably, the polyesteretheramide copolymer may have a hardness selected from about 63 Shore D, about 70 Shore D, and about 72 Shore D. The single polymeric layer may contain at least about 2 weight percent polyamide such as nylon 12, nylon 11, nylon 6, nylon 6/6, nylon 4/6, and

combinations thereof. The single polymeric layer may further contain at least about 2 weight percent polymer such as polyester copolymer, polyurethane copolymer, polyethylene, and combinations thereof. The polymeric layer may have at least about 40 weight percent polyesteretheramide copolymer and more preferably at least about 80 weight percent polyesteretheramide copolymer. The balloon may have from about 20 to about 80 weight percent nylon 12 and about 20 to about 80 weight percent polyesteretheramide copolymer, preferably about 60 weight percent nylon 12 and about 40 weight percent polyesteretheramide copolymer. Alternatively, the balloon may have about 25 to about 80 weight percent nylon 4/6 and about 20 to about 75 weight percent polyesteretheramide copolymer, preferably about 65 weight percent nylon 4/6 and about 35 weight percent polyesteretheramide copolymer.

The present invention also relates to a balloon for an angioplasty device having a single polymeric layer consisting essentially of a polyesteretheramide copolymer. The polyesteretheramide copolymer may be a block or random copolymer. The polyesteretheramide copolymer may have a hardness of from about 45 Shore D to about 78 Shore D, preferably from about 55 Shore D to about 75 Shore D, and more preferably about 63 to about 72 Shore D. Even more preferably the polyesteretheramide copolymer may have a hardness selected from 63 Shore D, 70 Shore D, and 72 Shore D. The balloon may consist of polyesteretheramide.

The present invention also relates to a balloon for an angioplasty device having a single polymeric layer having (a) at least 91 weight percent polyesteretheramide copolymer, (b) from 0 to 9 weight percent polyamide, and  
5 (c) from 0 to 9 weight percent of a polymer other than polyesteretheramide and polyamide. The balloon may have at least about 95 weight percent polyesteretheramide copolymer.

#### Description of the Drawings

10 FIG. 1 is a perspective view of an expander member of the present invention joined to the distal end of a catheter;

FIG. 2 is a cross-sectional view of a balloon form used to make expander members of the present invention;

15 FIG. 3 is a schematic view of a mold apparatus used to make expander members of the present invention;

FIG. 4 shows a response surface that details the effects of processing variables and material selection on balloon wall thickness for PEBAX 6333 balloons;

20 FIG. 5 shows a response surface that details the effects of processing variables and material selection on balloon burst pressure for PEBAX 6333 balloons;

FIG. 6 shows a response surface that details the effects of processing variables and material selection on  
25 balloon K-stat for PEBAX 6333 balloons;

FIG. 7 shows a response surface that details the effects of processing variables and material selection on balloon hoop stress for PEBAX 6333 balloons;

FIG. 8 shows a response surface that details the effects of processing variables and material selection on balloon wall thickness for PEBAX 7033 balloons;

FIG. 9 shows a response surface that details the effects of processing variables and material selection on balloon burst pressure for PEBAX 7033 balloons;

FIG. 10 shows a response surface that details the effects of processing variables and material selection on balloon K-stat 7033 for PEBAX 7033 balloons;

FIG. 11 shows a response surface that details the effects of processing variables and material selection on balloon hoop stress for PEBAX 7033 balloons;

FIG. 12 shows a response surface that details the effects of processing variables and material selection on balloon wall thickness for PEBAX 7233 balloons;

FIG. 13 shows a response surface that details the effects of processing variables and material selection on balloon burst pressure for PEBAX 7233 balloons;

FIG. 14 shows a response surface that details the effects of processing variables and material selection on balloon K-stat for PEBAX 7233 balloons; and

FIG. 15 shows a response surface that details the effects of processing variables and material selection on balloon hoop stress for PEBAX 7233 balloons.

#### Description of the Preferred Embodiments

With reference to FIG. 1, expander member 2 is attached to the distal end of a catheter shaft 4. The expander member 2, otherwise known as a balloon, has a single polymeric layer 6 which surrounds the catheter shaft 4. The expander member 2 shown is bonded at two

bonding sites 8a,b by thermal bonding, by laser bonding, with adhesives, or by other methods known in the art.

The expander members of the present invention contain polyesteretheramide copolymer. The structure of these polymers consists of regular and linear chains of rigid polyamide blocks and flexible polyether blocks. Such copolymers may be described by the following formula:



where PA is a polyamide block; and

where PE is a polyether block.

Polyesteretheramide copolymer materials are sold under the trademark PEBAX by Atochem Inc. of Glen Rock, New Jersey. Properties of several grades of PEBAX are disclosed in Atochem's brochure entitled "PEBAX Polyether Block Amide" (December 1987).

The expander member of the present invention may contain polyamide. Polyamide materials include nylon 12, nylon 11, nylon 6, nylon 6/6, and nylon 4/6. Such materials are sold under the trademark ZYTEL<sup>®</sup> by Dupont.

The expander member of the present invention may further contain a polymer other than polyesteretheramide copolymer or polyamide, such as polyester copolymer, polyurethane copolymer, polyethylene, and combinations thereof.

The single polymeric layer making up the expander member may be a blend of suitable materials. Such a blend may be created by mixing the desired resins and



then extruding these resins to form a parison. The single layer can also be a graft copolymer. Such a graft copolymer can be formed, for example, by reacting polyamide (such as Nylon 12) with polyphenylether graft maleic anhydride (PPE-graft-MA). So called polymer alloys, and the like, are also included within the purview of this application.

The expander member of the present invention may be formed by first generating a parison in an extruder. The parison will typically have an inside diameter of from about .01 to .031 inches (0.025 to 0.079 cm), and a wall thickness of from about .0035 to .015 inches (.0089 to 0.038 cm).

Hot water treated molding devices may then be utilized to blow mold the expander members of the present invention. Tubing of the desired material and having a required size and thickness is inserted into a balloon processing mold and heated to a temperature of from about 200-212°F (93-100°C). Weight may be added to the mold as desired. The tubing is subjected to longitudinal tension and high-pressure nitrogen 380-500 psi is introduced into the tubing in the mold. The mold remains in a hot water bath for a predetermined period of time of from about 10-45 seconds, preferably 25 seconds. The mold is then removed and placed in a cooling pot for a predetermined period of time of from about 20-40 seconds, preferably 30 seconds, after which the mold may be opened and the balloon removed.

In an alternative process, the balloons are formed in balloon blow molding machines. The tubing is inserted

into the mold and the ends of the tubing secured into mold gaskets. The tubing is thereafter heated in the range of 190-220°F (87-104°C) for about 10 to 45 seconds, preferably 25-30 seconds, and the heated tubing is  
5 subjected to longitudinal tension and expanded 1-2 times its length in the axial direction. The stretched tubing is pressurized with nitrogen in the range of about 350-500 psi and heat treated in the mold for about 10-20 seconds at about 250-280°F (121-138°C), preferably about  
10 260-270°F (127-132°C). The mold is then cooled to room temperature and allowed to set at room temperature in the mold under pressure for approximately 10 to 15 seconds. Thereafter, the system can be depressurized and the balloon removed from the mold.

15 Examples

Balloons were made of polyesteretheramide block copolymer and then tested to determine certain characteristics.

Examples 1-180

20 180 balloons were made according to the following process:

Parisons of 100 weight percent polyesteretheramide block copolymer were extruded. The parisons had inside diameters of about .015 inches to about .023 inches, wall  
25 thicknesses of about .006 inches to about .010 inches, and lengths of about 18 inches.

The parisons were placed in the mold apparatus illustrated in FIGS. 2 and 3. As shown in FIG. 2, the balloon form 8 had a void 10 corresponding to the final  
30 shape of the expander member. The void was made up by a

proximal form 24, a body form 26, and a distal form 28. With reference to FIG. 3, the distal end of the parison was inserted into the proximal end 14 of the mold apparatus 12, and pushed through the proximal form 24, the body form 26, and the distal form 28 until it exited the distal end 16 of the mold section. Cap 18 was then placed over the distal end 16 of the apparatus 12 thereby clamping and sealing the distal end of the parison. The mold was then placed in a handle 20 such that the proximal end of the parison freely extended from the handle 20. Weights 22 were then placed over the proximal end of the parison and onto the mold.

The open proximal end of the parison was then connected to a pressurized nitrogen source by a Touhy Borst clamp. The nitrogen source was capable of achieving maximum pressures of 1,000 psi. The nitrogen source was then opened to varying degrees of between 350-500 psi and the mold was placed in a bath of hot water (212°F). The hot water bath warmed the parison. The freely extending proximal end of the parison was held by hand such that only about the distal form 28 was under water, until the mold dropped due to longitudinal stretching and the distal end of the parison expanded radially (about 15-30 seconds). Still holding the mold by hand, the mold continued to drop until it was entirely under water and the proximal end of the balloon expanded radially (about an additional 1-10 seconds).

The mold was then removed from the hot water bath and placed in a cold water bath of about 60-75°F for

about 30 seconds. The nitrogen was then shut off, and the balloon was removed from the mold.

The balloons were tested by attaching the balloons to a pressurized nitrogen source in a 37°C water bath, expanding the balloons under several predetermined pressures of nitrogen (50 psi, 100 psi, 150 psi, and burst pressure), and then measuring several dimensions and the burst pressure of the balloons. Dimensions were measured with a snap gauge.

Tables 1-18 below list certain parameters of the process utilized to make the subject balloons (hot pot temperature, cold pot temperature, weight added to mold, and nitrogen pressure). The tables also show results of the testing of the expander members. K stat was calculated as follows:  $(\text{Burst pressure}) - ((K \text{ Stat}) (\text{Burst Pressure Standard Deviation}))$ . Hoop stress was calculated as follows:  $(\text{Balloon Burst Pressure}) (\text{Balloon Diameter}) / (2) (\text{Balloon Wall Thickness})$ .

Table 1

**PEBAX GRADE: 6333**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 212° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 250 GRAMS  
 NITROGEN 400 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 1           | 0.001250                             | 0.001300                                | 0.001250                              | .017x.031               | 0.1120                   | 0.1200                    | 0.1260                    | 255                  |
| 2           | 0.001350                             | 0.001300                                | 0.001300                              | .017x.031               | 0.1120                   | 0.1200                    | 0.1250                    | 266                  |
| 3           | 0.001400                             | 0.001300                                | 0.001300                              | .017x.031               | 0.1125                   | 0.1210                    | 0.1250                    | 269                  |
| 4           | 0.001300                             | 0.001400                                | 0.001250                              | .017x.031               | 0.1120                   | 0.1200                    | 0.1250                    | 270                  |
| 5           | 0.001350                             | 0.001400                                | 0.001300                              | .017x.031               | 0.1130                   | 0.1200                    | 0.1260                    | 270                  |
| 6           | 0.001350                             | 0.001400                                | 0.001300                              | .017x.031               |                          |                           |                           | 252                  |
| 7           | 0.001350                             | 0.001400                                | 0.001300                              | .017x.031               |                          |                           |                           | 268                  |
| 8           | 0.001300                             | 0.001400                                | 0.001300                              | .017x.031               |                          |                           |                           | 270                  |
| 9           | 0.001300                             | 0.001350                                | 0.001300                              | .017x.031               |                          |                           |                           | 268                  |
| 10          | 0.001350                             | 0.001450                                | 0.001300                              | .017x.031               |                          |                           |                           | 280                  |
| Average     | 0.001330                             | 0.001370                                | 0.001290                              | .017x.031               | 0.11230                  | 0.12020                   | 0.12540                   | 266.8                |
| Standard    | 4.2164E-05                           | 5.37484E-05                             | 2.10819E-05                           |                         | 0.000447                 | 0.000447                  | 0.000548                  | 7.9693859            |

Calculated K-stat (psi):

225.3353

Calculated Hoop Stress (psi):

24112

Table 2  
**PEBAX GRADE: 6333**  
 BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 212° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 300 GRAMS  
 NITROGEN 480 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 11          | 0.00190                              | 0.00190                                 | 0.00190                               | .015X.035               | 0.1080                   | 0.1180                    | 0.1230                    | 300                  |
| 12          | 0.00180                              | 0.00185                                 | 0.00180                               | .015X.035               | 0.1090                   | 0.1180                    | 0.1220                    | 275                  |
| 13          | 0.00170                              | 0.00185                                 | 0.00165                               | .015X.035               | 0.1090                   | 0.1180                    | 0.1220                    | 296                  |
| 14          | 0.00180                              | 0.00180                                 | 0.00180                               | .015X.035               | 0.1075                   | 0.1170                    | 0.1220                    | 285                  |
| 15          | 0.00190                              | 0.00195                                 | 0.00170                               | .015X.035               | 0.1080                   | 0.1180                    | 0.1220                    | 285                  |
| 16          | 0.00180                              | 0.00185                                 | 0.00160                               | .015X.035               |                          |                           |                           | 300                  |
| 17          | 0.00180                              | 0.00180                                 | 0.00180                               | .015X.035               |                          |                           |                           | 293                  |
| 18          | 0.00190                              | 0.00185                                 | 0.00170                               | .015X.035               |                          |                           |                           | 315                  |
| 19          | 0.00185                              | 0.00180                                 | 0.00165                               | .015X.035               |                          |                           |                           | 285                  |
| 20          | 0.00170                              | 0.00170                                 | 0.00170                               | .015X.035               |                          |                           |                           | 285                  |
| Average     | 0.001815                             | 0.001835                                | 0.00173                               | .015X.035               | 0.1083                   | 0.1178                    | 0.1222                    | 291.9                |
| Standard    | 7.47E-05                             | 6.687E-05                               | 9.18937E-05                           |                         | 0.000671                 | 0.000447                  | 0.000447                  | 11.34754             |

Calculated K-stat (psi):  
 Calculated Hoop Stress (psi):

232.8587  
 28594

Table 3

**PEBAX GRADE: 6333**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 212° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 250 GRAMS  
 NITROGEN 440 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 21          | 0.00170                              | 0.00170                                 | 0.00170                               | .017X.034               | 0.110                    | 0.121                     | 0.125                     | 293                  |
| 22          | 0.00160                              | 0.00160                                 | 0.00160                               | .017X.034               | 0.111                    | 0.120                     | 0.126                     | 270                  |
| 23          | 0.00170                              | 0.00170                                 | 0.00170                               | .017X.034               | 0.111                    | 0.120                     | 0.125                     | 293                  |
| 24          | 0.00170                              | 0.00170                                 | 0.00170                               | .017X.034               | 0.110                    | 0.121                     | 0.125                     | 291                  |
| 25          | 0.00160                              | 0.00160                                 | 0.00160                               | .017X.034               | 0.110                    | 0.121                     | 0.125                     | 293                  |
| 26          | 0.00155                              | 0.00150                                 | 0.00150                               | .017X.034               |                          |                           |                           | 283                  |
| 27          | 0.00170                              | 0.00170                                 | 0.00170                               | .017X.034               |                          |                           |                           | 293                  |
| 28          | 0.00160                              | 0.00160                                 | 0.00160                               | .017X.034               |                          |                           |                           | 293                  |
| 29          | 0.00170                              | 0.00170                                 | 0.00170                               | .017X.034               |                          |                           |                           | 287                  |
| 30          | 0.00170                              | 0.00170                                 | 0.00170                               | .017X.034               |                          |                           |                           | 293                  |
| Average     | 0.001655                             | 0.001650                                | 0.001650                              | .017X.034               | 0.11040                  | 0.12060                   | 0.12520                   | 288.9                |
| Standard    | 5.99E-05                             | 7.071E-05                               | 7.07107E-05                           |                         | 0.000548                 | 0.000548                  | 0.000447                  | 7.460265             |

Calculated K-stat (psi):

250.0842

Calculated Hoop Stress (psi):

21052

Table 4

**PEBAX GRADE: 6333**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

**PARAMETERS:**

HOT POT: 210° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 300 GRAMS  
 NITROGEN 320 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 31          | 0.00140                              | 0.00140                                 | 0.00140                               | .020X.032               | 0.117                    | 0.123                     | 0.128                     | 251                  |
| 32          | 0.00140                              | 0.00140                                 | 0.00140                               | .020X.032               | 0.117                    | 0.123                     | 0.129                     | 249                  |
| 33          | 0.00125                              | 0.00125                                 | 0.00120                               | .020X.032               | 0.117                    | 0.123                     | 0.129                     | 253                  |
| 34          | 0.00135                              | 0.00130                                 | 0.00120                               | .020X.032               | 0.116                    | 0.123                     | 0.129                     | 251                  |
| 35          | 0.00140                              | 0.00130                                 | 0.00130                               | .020X.032               | 0.116                    | 0.123                     | 0.128                     | 253                  |
| 36          | 0.00140                              | 0.00140                                 | 0.00135                               | .020X.032               |                          |                           |                           | 243                  |
| 37          | 0.00140                              | 0.00135                                 | 0.00135                               | .020X.032               |                          |                           |                           | 223                  |
| 38          | 0.00130                              | 0.00130                                 | 0.00130                               | .020X.032               |                          |                           |                           | 253                  |
| 39          | 0.00135                              | 0.00135                                 | 0.00135                               | .020X.032               |                          |                           |                           | 223                  |
| 40          | 0.00135                              | 0.00135                                 | 0.00125                               | .020X.032               |                          |                           |                           | 253                  |
| Average     | 0.001360                             | 0.00134                                 | 0.0013100                             | .020X.032               | 0.1166                   | 0.123                     | 0.1286                    | 245.2                |
| Standard    | 5.16E-05                             | 5.164E-05                               | 7.37865E-05                           |                         | 0.000548                 | 1.86E-09                  | 0.000548                  | 12.0904              |

Calculated K-stat (psi):

182.2936

Calculated Hoop Stress (psi):

22176



Table 5

**PEBAX GRADE: 6333**  
BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 210° F.  
COLD POT: ROOM TEMP.  
WEIGHT: 350 GRAMS  
NITROGEN 400 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 41          | 0.00160                              | 0.00160                                 | 0.00160                               | .020X.035               | 0.115                    | 0.125                     | 0.130                     | 253                  |
| 42          | 0.00170                              | 0.00170                                 | 0.00170                               | .020X.035               | 0.117                    | 0.125                     | 0.130                     | 263                  |
| 43          | 0.00160                              | 0.00170                                 | 0.00170                               | .020X.035               | 0.117                    | 0.125                     | 0.130                     | 269                  |
| 44          | 0.00140                              | 0.00150                                 | 0.00150                               | .020X.035               | 0.118                    | 0.126                     | 0.131                     | 253                  |
| 45          | 0.00145                              | 0.00155                                 | 0.00150                               | .020X.035               | 0.114                    | 0.123                     | 0.129                     | 250                  |
| 46          | 0.00160                              | 0.00160                                 | 0.00160                               | .020X.035               |                          |                           |                           | 269                  |
| 47          | 0.00150                              | 0.00150                                 | 0.00140                               | .020X.035               |                          |                           |                           | 268                  |
| 48          | 0.00140                              | 0.00140                                 | 0.00140                               | .020X.035               |                          |                           |                           | 239                  |
| 49          | 0.00150                              | 0.00150                                 | 0.00150                               | .020X.035               |                          |                           |                           | 257                  |
| 50          | 0.00150                              | 0.00150                                 | 0.00150                               | .020X.035               |                          |                           |                           | 257                  |
| Average     | 0.001525                             | 0.001555                                | 0.001540                              | .020X.035               | 0.1162                   | 0.1248                    | 0.13                      | 257.8                |
| Standard    | 9.79E-05                             | 9.56E-05                                | 0.000107497                           |                         | 0.001643                 | 0.001095                  | 0.000707                  | 9.681598             |

207.4266

Calculated K-stat (psi):

21097

Calculated Hoop Stress (psi):

Table 6

## PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 200° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 250 GRAMS  
 NITROGEN 400 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 51          | 0.00165                              | 0.00165                                 | 0.0016                                | .023X.035               | 0.118                    | 0.127                     | 0.136                     | 223                  |
| 52          | 0.00130                              | 0.00130                                 | 0.0013                                | .023X.035               | 0.118                    | 0.130                     | 0.138                     | 223                  |
| 53          | 0.00130                              | 0.00140                                 | 0.0013                                | .023X.035               | 0.117                    | 0.127                     | 0.135                     | 239                  |
| 54          | 0.00140                              | 0.00140                                 | 0.0014                                | .023X.035               | 0.118                    | 0.128                     | 0.136                     | 239                  |
| 55          | 0.00150                              | 0.00160                                 | 0.0016                                | .023X.035               | 0.118                    | 0.127                     | 0.136                     | 239                  |
| 56          | 0.00150                              | 0.00150                                 | 0.0015                                | .023X.035               |                          |                           |                           | 250                  |
| 57          | 0.00140                              | 0.00140                                 | 0.0014                                | .023X.035               |                          |                           |                           | 250                  |
| 58          | 0.00130                              | 0.00130                                 | 0.0013                                | .023X.035               |                          |                           |                           | 238                  |
| 59          | 0.00130                              | 0.00130                                 | 0.0013                                | .023X.035               |                          |                           |                           | 253                  |
| 60          | 0.00130                              | 0.00130                                 | 0.0013                                | .023X.035               |                          |                           |                           | 239                  |
| Average     | 0.001395                             | 0.001415                                | 0.0014                                | .023X.035               | 0.1178                   | 0.1278                    | 0.1362                    | 239.3                |
| Standard    | 0.000121                             | 0.0001292                               | 0.000124722                           |                         | 0.000447                 | 0.001304                  | 0.001095                  | 10.27456             |

Calculated K-stat (psi):  
 Calculated Hoop Stress (psi):

185.8414  
 21922

Table 7

**PEBAX GRADE: 6333**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 210° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 350 GRAMS  
 NITROGEN 420 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 61          | 0.00150                              | 0.00150                                 | 0.0015                                | .023X.038               | 0.118                    | 0.126                     | 0.134                     | 253                  |
| 62          | 0.00150                              | 0.00150                                 | 0.0015                                | .023X.038               | 0.119                    | 0.126                     | 0.135                     | 253                  |
| 63          | 0.00160                              | 0.00160                                 | 0.0016                                | .023X.038               | 0.121                    | 0.130                     | 0.138                     | 260                  |
| 64          | 0.00160                              | 0.00160                                 | 0.0016                                | .023X.038               | 0.120                    | 0.127                     | 0.138                     | 245                  |
| 65          | 0.00140                              | 0.00140                                 | 0.0014                                | .023X.038               | 0.120                    | 0.127                     | 0.139                     | 253                  |
| 66          | 0.00160                              | 0.00160                                 | 0.0015                                | .023X.038               |                          |                           |                           | 253                  |
| 67          | 0.00160                              | 0.00160                                 | 0.0016                                | .023X.038               |                          |                           |                           | 253                  |
| 68          | 0.00160                              | 0.00160                                 | 0.0016                                | .023X.038               |                          |                           |                           | 263                  |
| 69          | 0.00170                              | 0.00170                                 | 0.0017                                | .023X.038               |                          |                           |                           | 253                  |
| 70          | 0.00145                              | 0.00145                                 | 0.0015                                | .023X.038               |                          |                           |                           | 258                  |
| Average     | 0.001555                             | 0.001555                                | 0.00155                               | .023X.038               | 0.1196                   | 0.1272                    | 0.1368                    | 254.4                |
| Standard    | 8.96E-05                             | 8.96E-05                                | 8.49837E-05                           |                         | 0.00114                  | 0.001643                  | 0.002168                  | 4.926121             |

Calculated K-stat (psi):  
 Calculated Hoop Stress (psi):

228.7694  
 20810

Table 8

**PEBAX GRADE: 7033**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 212° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 250 GRAMS  
 NITROGEN 460 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 71          | 0.00145                              | 0.00155                                 | 0.00155                               | .017X.034               | 0.1110                   | 0.119                     | 0.123                     | 305                  |
| 72          | 0.00150                              | 0.00150                                 | 0.00150                               | .017X.034               | 0.1100                   | 0.120                     | 0.124                     | 307                  |
| 73          | 0.00145                              | 0.00150                                 | 0.00155                               | .017X.034               | 0.1100                   | 0.118                     | 0.123                     | 293                  |
| 74          | 0.00140                              | 0.00150                                 | 0.00150                               | .017X.034               | 0.1100                   | 0.120                     | 0.123                     | 323                  |
| 75          | 0.00145                              | 0.00155                                 | 0.00150                               | .017X.034               | 0.1100                   | 0.118                     | 0.124                     | 309                  |
| 76          | 0.00160                              | 0.00150                                 | 0.00150                               | .017X.034               |                          |                           |                           | 295                  |
| 77          | 0.00150                              | 0.00140                                 | 0.00145                               | .017X.034               |                          |                           |                           | 323                  |
| 78          | 0.00140                              | 0.00140                                 | 0.00140                               | .017X.034               |                          |                           |                           | 293                  |
| 79          | 0.00150                              | 0.00150                                 | 0.00150                               | .017X.034               |                          |                           |                           | 320                  |
| 80          | 0.00150                              | 0.00150                                 | 0.00150                               | .017X.034               |                          |                           |                           | 303                  |
| Average     | 0.001475                             | 0.00149                                 | 0.001495                              | .017X.034               | 0.1102                   | 0.119                     | 0.1234                    | 307.1                |
| Standard    | 5.89E-05                             | 5.164E-05                               | 4.3798E-05                            |                         | 0.000447                 | 0.001                     | 0.000548                  | 11.74214             |

Calculated K-stat (psi):

246.0057

Calculated Hoop Stress (psi):

24776

Table 9

**PEBAX GRADE: 7033**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 205° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 250 GRAMS  
 NITROGEN 380 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 81          | 0.00115                              | 0.00115                                 | 0.00115                               | .020X.032               | 0.114                    | 0.120                     | 0.125                     | 270                  |
| 82          | 0.00125                              | 0.00125                                 | 0.00115                               | .020X.032               | 0.113                    | 0.120                     | 0.125                     | 270                  |
| 83          | 0.00130                              | 0.00130                                 | 0.00120                               | .020X.032               | 0.114                    | 0.120                     | 0.125                     | 270                  |
| 84          | 0.00120                              | 0.00120                                 | 0.00110                               | .020X.032               | 0.113                    | 0.120                     | 0.125                     | 270                  |
| 85          | 0.00120                              | 0.00120                                 | 0.00115                               | .020X.032               | 0.115                    | 0.121                     | 0.126                     | 270                  |
| 86          | 0.00115                              | 0.00115                                 | 0.00110                               | .020X.032               |                          |                           |                           | 250                  |
| 87          | 0.00115                              | 0.00120                                 | 0.00110                               | .020X.032               |                          |                           |                           | 271                  |
| 88          | 0.00115                              | 0.00120                                 | 0.00115                               | .020X.032               |                          |                           |                           | 270                  |
| 89          | 0.00125                              | 0.00120                                 | 0.00120                               | .020X.032               |                          |                           |                           | 270                  |
| 90          | 0.00120                              | 0.00115                                 | 0.00115                               | .020X.032               |                          |                           |                           | 269                  |
| Average     | 0.0012                               | 0.0012                                  | 0.001145                              | .020X.032               | 0.1138                   | 0.1202                    | 0.1252                    | 268                  |
| Standard    | 5.27E-05                             | 4.714E-05                               | 3.68932E-05                           |                         | 0.000837                 | 0.000447                  | 0.000447                  | 6.342099             |

Calculated K-stal (psi):  
 Calculated Hoop Stress (psi):

235.0021  
 26844

Table 10

**PEBAX GRADE: 7033**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 212° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 250 GRAMS  
 NITROGEN 400 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 91          | 0.00130                              | 0.00135                                 | 0.00140                               | .020X.035               | 0.109                    | 0.119                     | 0.125                     | 295                  |
| 92          | 0.00130                              | 0.00135                                 | 0.00140                               | .020X.035               | 0.115                    | 0.124                     | 0.128                     | 300                  |
| 93          | 0.00130                              | 0.00135                                 | 0.00130                               | .020X.035               | 0.115                    | 0.122                     | 0.127                     | 289                  |
| 94          | 0.00130                              | 0.00135                                 | 0.00130                               | .020X.035               | 0.113                    | 0.124                     | 0.130                     | 298                  |
| 95          | 0.00130                              | 0.00140                                 | 0.00130                               | .020X.035               | 0.115                    | 0.124                     | 0.128                     | 283                  |
| 96          | 0.00135                              | 0.00135                                 | 0.00135                               | .020X.035               |                          |                           |                           | 297                  |
| 97          | 0.00140                              | 0.00140                                 | 0.00140                               | .020X.035               |                          |                           |                           | 297                  |
| 98          | 0.00140                              | 0.00140                                 | 0.00140                               | .020X.035               |                          |                           |                           | 297                  |
| 99          | 0.00140                              | 0.00130                                 | 0.00140                               | .020X.035               |                          |                           |                           | 290                  |
| 100         | 0.00130                              | 0.00130                                 | 0.00130                               | .020X.035               |                          |                           |                           | 290                  |
| Average     | 0.001335                             | 0.001355                                | 0.001355                              | .020X.035               | 0.1134                   | 0.1226                    | 0.1276                    | 293.6                |
| Standard    | 4.74E-05                             | 3.689E-05                               | 4.97214E-05                           |                         | 0.002608                 | 0.002191                  | 0.001817                  | 5.337498             |

Calculated K-stat (psi):

265.829

Calculated Hoop Stress (psi):

26962

Table 11

**PEBAX GRADE: 7033**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 210° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 350 GRAMS  
 NITROGEN 400 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 101         | 0.0014                               | 0.0014                                  | 0.00140                               | .023X.035               | 0.115                    | 0.121                     | 0.127                     | 298                  |
| 102         | 0.0013                               | 0.0013                                  | 0.00125                               | .023X.035               | 0.117                    | 0.126                     | 0.134                     | 253                  |
| 103         | 0.0013                               | 0.0013                                  | 0.00120                               | .023X.035               | 0.117                    | 0.126                     | 0.131                     | 275                  |
| 104         | 0.0013                               | 0.0013                                  | 0.00130                               | .023X.035               | 0.118                    | 0.126                     | 0.132                     | 238                  |
| 105         | 0.0013                               | 0.0013                                  | 0.00140                               | .023X.035               | 0.116                    | 0.127                     | 0.133                     | 281                  |
| 106         | 0.0013                               | 0.0013                                  | 0.00140                               | .023X.035               |                          |                           |                           | 280                  |
| 107         | 0.0013                               | 0.0013                                  | 0.00140                               | .023X.035               |                          |                           |                           | 269                  |
| 108         | 0.0012                               | 0.0012                                  | 0.00130                               | .023X.035               |                          |                           |                           | 280                  |
| 109         | 0.0012                               | 0.0012                                  | 0.00125                               | .023X.035               |                          |                           |                           | 283                  |
| 110         | 0.0012                               | 0.0012                                  | 0.00125                               | .023X.035               |                          |                           |                           | 283                  |
| Average     | 0.00128                              | 0.00128                                 | 0.001315                              | .023X.035               | 0.1166                   | 0.1252                    | 0.1314                    | 274                  |
| Standard    | 6.32E-05                             | 6.325E-05                               | 7.83511E-05                           |                         | 0.00114                  | 0.002387                  | 0.002702                  | 17.06849             |

Calculated K-stat (psi):

185.1926

Calculated Hoop Stress (psi):

26800

Table 12

**PEBAX GRADE: 7033**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 210° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 350 GRAMS  
 NITROGEN 420 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 111         | 0.00150                              | 0.0015                                  | 0.0014                                | .023X.038               | 0.119                    | 0.125                     | 0.130                     | 310                  |
| 112         | 0.00160                              | 0.0016                                  | 0.0016                                | .023X.038               | 0.118                    | 0.125                     | 0.130                     | 300                  |
| 113         | 0.00180                              | 0.0016                                  | 0.0016                                | .023X.038               | 0.118                    | 0.125                     | 0.130                     | 293                  |
| 114         | 0.00150                              | 0.0015                                  | 0.0015                                | .023X.038               | 0.118                    | 0.126                     | 0.131                     | 283                  |
| 115         | 0.00150                              | 0.0015                                  | 0.0015                                | .023X.038               | 0.119                    | 0.125                     | 0.130                     | 280                  |
| 116         | 0.00150                              | 0.0016                                  | 0.0015                                | .023X.038               |                          |                           |                           | 300                  |
| 117         | 0.00145                              | 0.0015                                  | 0.0015                                | .023X.038               |                          |                           |                           | 310                  |
| 118         | 0.00160                              | 0.0016                                  | 0.0016                                | .023X.038               |                          |                           |                           | 298                  |
| 119         | 0.00150                              | 0.0015                                  | 0.0015                                | .023X.038               |                          |                           |                           | 298                  |
| 120         | 0.00145                              | 0.0015                                  | 0.0015                                | .023X.038               |                          |                           |                           | 313                  |
| Average     | 0.00152                              | 0.00154                                 | 0.00152                               | .023X.038               | 0.1184                   | 0.1252                    | 0.1302                    | 298.5                |
| Standard    | 5.87E-05                             | 5.164E-05                               | 6.32456E-05                           |                         | 0.000548                 | 0.000447                  | 0.000447                  | 11.01766             |

Calculated K-stat (psi):

241.1751

Calculated Hoop Stress (psi):

24586



Table 13

**PEBAX GRADE: 7233**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 212° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 300 GRAMS  
 NITROGEN 460 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 121         | 0.00110                              | 0.00120                                 | 0.00110                               | .017x.031               | 0.108                    | 0.116                     | 0.120                     | 330                  |
| 122         | 0.00120                              | 0.00135                                 | 0.00120                               | 0.17x0.31               | 0.106                    | 0.115                     | 0.119                     | 345                  |
| 123         | 0.00130                              | 0.00140                                 | 0.00135                               | 0.17x0.31               | 0.106                    | 0.116                     | 0.120                     | 300                  |
| 124         | 0.00130                              | 0.00130                                 | 0.00120                               | 0.17x0.31               | 0.106                    | 0.116                     | 0.120                     | 345                  |
| 125         | 0.00130                              | 0.00130                                 | 0.00125                               | 0.17x0.31               | 0.108                    | 0.116                     | 0.120                     | 360                  |
| 126         | 0.00135                              | 0.00130                                 | 0.00120                               | 0.17x0.31               |                          |                           |                           | 345                  |
| 127         | 0.00145                              | 0.00130                                 | 0.00130                               | 0.17x0.31               |                          |                           |                           | 375                  |
| 128         | 0.00130                              | 0.00130                                 | 0.00130                               | 0.17x0.31               |                          |                           |                           | 330                  |
| 129         | 0.00145                              | 0.00130                                 | 0.00140                               | 0.17x0.31               |                          |                           |                           | 300                  |
| 130         | 0.00140                              | 0.00140                                 | 0.00135                               | 0.17x0.31               |                          |                           |                           | 345                  |
| Average     | 0.001315                             | 0.001315                                | 0.001265                              | .017x.031               | 0.10680                  | 0.11580                   | 0.11980                   | 337.5                |
| Standard    | 0.000108                             | 5.798E-05                               | 9.14391E-05                           |                         | 0.001095                 | 0.000447                  | 0.000447                  | 23.71708             |

Calculated K-stat (psi):

214.1

Calculated Hoop Stress (psi):

29720

Table 14

## PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 212° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 350 GRAMS  
 NITROGEN 500 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 131         | 0.00150                              | 0.00150                                 | 0.0015                                | .017X.034               | 0.11                     | 0.116                     | 0.121                     | 303                  |
| 132         | 0.00160                              | 0.00160                                 | 0.0016                                | .017X.034               | 0.11                     | 0.116                     | 0.121                     | 280                  |
| 133         | 0.00160                              | 0.00160                                 | 0.0016                                | .017X.034               | 0.11                     | 0.116                     | 0.121                     | 353                  |
| 134         | 0.00155                              | 0.00155                                 | 0.0015                                | .017X.034               | 0.11                     | 0.117                     | 0.120                     | 340                  |
| 135         | 0.00160                              | 0.00160                                 | 0.0016                                | .017X.034               | 0.11                     | 0.116                     | 0.121                     | 348                  |
| 136         | 0.00160                              | 0.00160                                 | 0.0016                                | .017X.034               |                          |                           |                           | 338                  |
| 137         | 0.00160                              | 0.00160                                 | 0.0016                                | .017X.034               |                          |                           |                           | 350                  |
| 138         | 0.00170                              | 0.00170                                 | 0.0017                                | .017X.034               |                          |                           |                           | 369                  |
| 139         | 0.00170                              | 0.00170                                 | 0.0017                                | .017X.034               |                          |                           |                           | 318                  |
| 140         | 0.00170                              | 0.00170                                 | 0.0017                                | .017X.034               |                          |                           |                           | 353                  |
| Average     | 0.001615                             | 0.001615                                | 0.00161                               | .017X.034               | 0.11                     | 0.1162                    | 0.1208                    | 335.2                |
| Standard    | 6.69E-05                             | 6.687E-05                               | 7.37865E-05                           |                         | 0.0                      | 0.000447                  | 0.000447                  | 27.01769             |

Calculated K-stat (psi):  
 Calculated Hoop Stress (psi):

194.627  
 24117

Table 15

**PEBAX GRADE: 7233**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

**PARAMETERS:**

HOT POT: 210° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 350 GRAMS  
 NITROGEN 400 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 141         | 0.00140                              | 0.00140                                 | 0.00140                               | .020X.035               | 0.112                    | 0.120                     | 0.125                     | 359                  |
| 142         | 0.00140                              | 0.00150                                 | 0.00150                               | .020X.035               | 0.112                    | 0.118                     | 0.125                     | 325                  |
| 143         | 0.00140                              | 0.00150                                 | 0.00150                               | .020X.035               | 0.113                    | 0.118                     | 0.123                     | 329                  |
| 144         | 0.00150                              | 0.00150                                 | 0.00150                               | .020X.035               | 0.111                    | 0.120                     | 0.123                     | 359                  |
| 145         | 0.00150                              | 0.00150                                 | 0.00150                               | .020X.035               | 0.113                    | 0.120                     | 0.124                     | 350                  |
| 146         | 0.00145                              | 0.00150                                 | 0.00150                               | .020X.035               |                          |                           |                           | 330                  |
| 147         | 0.00150                              | 0.00160                                 | 0.00160                               | .020X.035               |                          |                           |                           | 343                  |
| 148         | 0.00140                              | 0.00130                                 | 0.00130                               | .020X.035               |                          |                           |                           | 353                  |
| 148         | 0.00155                              | 0.00155                                 | 0.00155                               | .020X.035               |                          |                           |                           | 309                  |
| 150         | 0.00150                              | 0.00150                                 | 0.00150                               | .020X.035               |                          |                           |                           | 343                  |
| Average     | 0.00146                              | 0.001485                                | 0.001485                              | .020X.035               | 0.1122                   | 0.1192                    | 0.124                     | 340                  |
| Standard    | 5.68E-05                             | 8.182E-05                               | 8.18196E-05                           |                         | 0.000837                 | 0.001095                  | 0.001                     | 16.38427             |

Calculated K-stat (psi):

254.7528

Calculated Hoop Stress (psi):

27018

Table 16

## PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 205° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 320 GRAMS  
 NITROGEN 400 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 151         | 0.0013                               | 0.00125                                 | 0.001250                              | .020X.032               | 0.114                    | 0.119                     | 0.123                     | 357                  |
| 152         | 0.0013                               | 0.00135                                 | 0.001300                              | .020X.032               | 0.113                    | 0.119                     | 0.123                     | 359                  |
| 153         | 0.0013                               | 0.00120                                 | 0.001200                              | .020X.032               | 0.113                    | 0.119                     | 0.123                     | 359                  |
| 154         | 0.0012                               | 0.00125                                 | 0.001200                              | .020X.032               | 0.112                    | 0.119                     | 0.123                     | 369                  |
| 155         | 0.0013                               | 0.00120                                 | 0.001200                              | .020X.032               | 0.113                    | 0.118                     | 0.123                     | 353                  |
| 156         | 0.0012                               | 0.00125                                 | 0.001250                              | .020X.032               |                          |                           |                           | 343                  |
| 157         | 0.0014                               | 0.00135                                 | 0.001350                              | .020X.032               |                          |                           |                           | 359                  |
| 158         | 0.0013                               | 0.00130                                 | 0.001300                              | .020X.032               |                          |                           |                           | 359                  |
| 159         | 0.0012                               | 0.00120                                 | 0.001150                              | .020X.032               |                          |                           |                           | 361                  |
| 160         | 0.0013                               | 0.00130                                 | 0.001250                              | .020X.032               |                          |                           |                           | 313                  |
| Average     | 0.00126                              | 0.001265                                | 0.001245                              | .020X.032               | 0.113                    | 0.1188                    | 0.12300                   | 353.2                |
| Standard    | 4.9721E-05                           | 5.798E-05                               | 5.98609E-05                           |                         | 0.000707                 | 0.000447                  | 1.86E-09                  | 15.56206             |

Calculated K-stat (psi):

272.2306

Calculated Hoop Stress (psi):

33342

Table 17

**PEBAX GRADE: 7233**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT: 210° F.  
 COLD POT: ROOM TEMP.  
 WEIGHT: 380 GRAMS  
 NITROGEN 400 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 161         | 0.00140                              | 0.00140                                 | 0.00140                               | .023X.035               | 0.116                    | 0.122                     | 0.126                     | 329                  |
| 162         | 0.00150                              | 0.00150                                 | 0.00140                               | .023X.035               | 0.116                    | 0.122                     | 0.127                     | 329                  |
| 163         | 0.00140                              | 0.00140                                 | 0.00150                               | .023X.035               | 0.116                    | 0.123                     | 0.128                     | 330                  |
| 164         | 0.00140                              | 0.00140                                 | 0.00150                               | .023X.035               | 0.116                    | 0.123                     | 0.128                     | 270                  |
| 165         | 0.00135                              | 0.00135                                 | 0.00135                               | .023X.035               | 0.117                    | 0.124                     | 0.129                     | 343                  |
| 166         | 0.00140                              | 0.00140                                 | 0.00140                               | .023X.035               |                          |                           |                           | 300                  |
| 167         | 0.00140                              | 0.00140                                 | 0.00150                               | .023X.035               |                          |                           |                           | 345                  |
| 168         | 0.00140                              | 0.00140                                 | 0.00140                               | .023X.035               |                          |                           |                           | 329                  |
| 169         | 0.00140                              | 0.00140                                 | 0.00140                               | .023X.035               |                          |                           |                           | 330                  |
| 170         | 0.00140                              | 0.00140                                 | 0.00140                               | .023X.035               |                          |                           |                           | 330                  |
| Average     | 0.001405                             | 0.001405                                | 0.001425                              | .023X.035               | 0.1162                   | 0.1228                    | 0.1276                    | 323.5                |
| Standard    | 3.69E-05                             | 3.689E-05                               | 5.40062E-05                           |                         | 0.000447                 | 0.000837                  | 0.00114                   | 22.29723             |

Calculated K-stat (psi):

207.4875

Calculated Hoop Stress (psi):

28274

Table 18

**PEBAX GRADE: 7233**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

## PARAMETERS:

HOT POT:  
COLD POT: ROOM TEMP.  
WEIGHT: 350 GRAMS  
NITROGEN 420 PSI

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 171         | 0.00160                              | 0.00160                                 | 0.001550                              | .023X.038               | 0.114                    | 0.120                     | 0.126                     | 375                  |
| 172         | 0.00160                              | 0.00160                                 | 0.001600                              | .023X.038               | 0.115                    | 0.122                     | 0.126                     | 300                  |
| 173         | 0.00165                              | 0.00160                                 | 0.001500                              | .023X.038               | 0.119                    | 0.125                     | 0.128                     | 298                  |
| 174         | 0.00160                              | 0.00165                                 | 0.001600                              | .023X.038               | 0.116                    | 0.122                     | 0.127                     | 328                  |
| 175         | 0.00160                              | 0.00160                                 | 0.001600                              | .023X.038               | 0.116                    | 0.123                     | 0.126                     | 343                  |
| 176         | 0.00170                              | 0.00170                                 | 0.001700                              | .023X.038               |                          |                           |                           | 370                  |
| 177         | 0.00160                              | 0.00170                                 | 0.001600                              | .023X.038               |                          |                           |                           | 370                  |
| 178         | 0.00170                              | 0.00170                                 | 0.001700                              | .023X.038               |                          |                           |                           | 355                  |
| 179         | 0.00165                              | 0.00170                                 | 0.001650                              | .023X.038               |                          |                           |                           | 358                  |
| 180         | 0.00170                              | 0.00170                                 | 0.001700                              | .023X.038               |                          |                           |                           | 373                  |
| Average     | 0.00164                              | 0.001655                                | 0.00162                               | .023X.038               | 0.116                    | 0.1224                    | 0.1266                    | 347                  |
| Standard    | 4.59E-05                             | 4.972E-05                               | 6.74949E-05                           |                         | 0.001871                 | 0.001817                  | 0.000894                  | 29.23088             |

Calculated K-stat (psi): 194.9117  
Calculated Hoop Stress (psi): 25898

Examples 181-206

26 balloons were made according to the process described for Examples 1-180, except that the mold apparatus did not utilize weights 22 separately, but  
5 rather incorporated a preselected weight into handle 20.

The balloons were tested to measure distension and balloon burst strength. Distension is defined as the ratio of two balloon diameters. In this test, a balloon was inflated to a series of pressures. The diameter was  
10 measured at each pressure. The distension is the ratio of the diameter at the lowest pressure to the diameter at the highest pressure. Inflation was performed at 1 bar increments up to burst pressure.

To test the balloons, the balloons were first placed  
15 in temperature controlled water bath, and warmed for a minimum of 1 minute in water. The balloons were then attached to a pneumatic inflation/deflation device. A vacuum was created. Starting with a 4 bar pressure for 20 seconds, the balloon diameter and length were  
20 measured. The balloons were deflated, and the measurements were recorded. Increasing the pressure by 1 bar, the balloon diameters and lengths were measured. This procedure was repeated until the balloons bursted. The burst pressure and the type of burst profile were  
25 recorded.

Tables 19-21 below show the results of the testing of the expander members.

Table 19

**PEBAX GRADE 7233**

Tubing Dimensions (ID x OD): 0.48 x 0.81 mm

Balloon Dimensions (OD x length): 3.0 x 20 mm

Diameter Form: 3.00 mm

|     | DIAMETER (mm)  |      |     |      |      |      |      |      |      |      |  |      | Average |
|-----|----------------|------|-----|------|------|------|------|------|------|------|--|------|---------|
|     | Balloon Number |      |     |      |      |      |      |      |      |      |  |      |         |
|     | 181            | 182  | 183 | 184  | 185  | 186  | 187  | 188  | 189  | 190  |  |      |         |
| atm | 181            | 182  | 183 | 184  | 185  | 186  | 187  | 188  | 189  | 190  |  |      |         |
| 4   | 2.57           | 2.60 | 3   | 2.60 | 2.57 | 2.55 | 2.54 | 2.54 | 2.61 | 2.57 |  | 2.58 |         |
| 6   | 2.79           | 2.81 | 3   | 2.81 | 2.79 | 2.79 | 2.70 | 2.75 | 2.78 | 2.80 |  | 2.78 |         |
| 8   | 2.91           | 2.94 | 3   | 2.93 | 2.93 | 2.95 | 2.89 | 2.88 | 2.93 | 2.93 |  | 2.92 |         |
| 10  | 3.01           | 3.01 | 3   | 3.02 | 3.02 | 3.01 | 2.99 | 3.00 | 3.00 | 3.02 |  | 3.01 |         |
| 12  | 3.06           | 3.07 | 3   | 3.08 | 3.09 | 3.08 | 3.03 | 3.05 | 3.06 | 3.07 |  | 3.07 |         |
| 14  | 3.12           | 3.14 | 3   | 3.13 | 3.12 | 3.12 | 3.09 | 3.11 | 3.12 | 3.12 |  | 3.12 |         |
| 16  | 3.17           | 3.17 | 3   | 3.17 | 3.18 | 3.17 | 3.14 | 3.16 | 3.16 | 3.18 |  | 3.17 |         |
| 18  | 3.23           | 3.24 | 3   | 3.25 | 3.24 | 3.23 | 3.21 | 3.22 | 3.23 | 3.23 |  | 3.23 |         |

Average burst pressure      21.1 atm  
 Minimum burst pressure      20.0 atm  
 Maximum burst pressure      22.0 atm



Table 20

**PEBAX GRADE 7233**

Tubing Dimensions (ID x OD): 0.48 x 0.82 mm

Balloon Dimensions (OD x length): 3.0 x 20 mm

Diameter Form: 3.25 mm

|     | DIAMETER (mm)  |      |      |      |      |      |      |      |  |  |  |  |  |      | Average |
|-----|----------------|------|------|------|------|------|------|------|--|--|--|--|--|------|---------|
|     | Balloon Number |      |      |      |      |      |      |      |  |  |  |  |  |      |         |
|     | 191            | 192  | 193  | 194  | 195  | 196  | 197  | 198  |  |  |  |  |  |      |         |
| atm | 2.73           | 2.74 | 2.66 | 2.71 | 2.69 | 2.71 | 2.70 | 2.77 |  |  |  |  |  |      |         |
| 4   | 2.73           | 2.74 | 2.66 | 2.71 | 2.69 | 2.71 | 2.70 | 2.77 |  |  |  |  |  | 2.71 |         |
| 6   | 2.97           | 2.93 | 2.89 | 2.92 | 2.92 | 2.94 | 2.97 | 3.01 |  |  |  |  |  | 2.94 |         |
| 8   | 3.12           | 3.06 | 3.03 | 3.08 | 3.06 | 3.07 | 3.08 | 3.12 |  |  |  |  |  | 3.08 |         |
| 10  | 3.18           | 3.12 | 3.15 | 3.16 | 3.12 | 3.17 | 3.18 | 3.19 |  |  |  |  |  | 3.16 |         |
| 12  | 3.23           | 3.20 | 3.22 | 3.23 | 3.19 | 3.23 | 3.23 | 3.26 |  |  |  |  |  | 3.22 |         |
| 14  | 3.30           | 3.27 | 3.27 | 3.27 | 3.25 | 3.28 | 3.28 | 3.33 |  |  |  |  |  | 3.28 |         |
| 16  | 3.33           | 3.31 | 3.31 | 3.30 | 3.29 | 3.32 | 3.32 | 3.36 |  |  |  |  |  | 3.32 |         |
| 18  | 3.39           | 3.33 | 3.37 | 3.37 | 3.36 | 3.40 | 3.39 | 3.43 |  |  |  |  |  | 3.38 |         |

Average burst pressure      21.4 atm  
 Minimum burst pressure      20.0 atm  
 Maximum burst pressure      22.0 atm

Table 21

**PEBAX GRADE 7233**

Tubing Dimensions (ID x OD): 0.65 x 0.90 mm

Balloon Dimensions (OD x length): 3.0 x 20 mm

Diameter Form: 3.25 mm

|     | DIAMETER (mm)  |      |      |      |      |      |      |      |  |  |  |  |  | Average |
|-----|----------------|------|------|------|------|------|------|------|--|--|--|--|--|---------|
|     | Balloon Number |      |      |      |      |      |      |      |  |  |  |  |  |         |
|     | 199            | 200  | 201  | 202  | 203  | 204  | 205  | 206  |  |  |  |  |  |         |
| atm | 2.91           | 2.92 | 2.94 | 2.91 | 2.87 | 2.85 | 2.93 | 2.99 |  |  |  |  |  | 2.92    |
| 4   | 3.17           | 3.15 | 3.16 | 3.13 | 3.14 | 3.10 | 3.17 | 3.19 |  |  |  |  |  | 3.15    |
| 6   | 3.28           | 3.32 | 3.29 | 3.29 | 3.28 | 3.25 | 3.31 | 3.33 |  |  |  |  |  | 3.29    |
| 8   | 3.40           | 3.44 | 3.41 | 3.39 | 3.40 | 3.36 | 3.42 | 3.44 |  |  |  |  |  | 3.41    |
| 10  | 3.52           | 3.52 | 3.49 | 3.52 | 3.51 | 3.48 | 3.52 | 3.53 |  |  |  |  |  | 3.51    |
| 12  | 3.66           | 3.65 | 3.64 | 3.65 | 3.65 | 3.62 | 3.66 | 3.66 |  |  |  |  |  | 3.65    |
| 14  | 3.79           | 3.79 | 3.82 | 3.83 | 3.80 | 3.78 | 3.82 | 3.85 |  |  |  |  |  | 3.81    |
| 16  | 4.05           | -    | -    | -    | 4.06 | 4.08 | 4.05 | 4.17 |  |  |  |  |  | 4.08    |

Average burst pressure  
 Minimum burst pressure  
 Maximum burst pressure

19.3 atm  
 18.0 atm  
 20.0 atm

Examples 207-236

30 balloons were made according to the procedure described above for Examples 1-180, except that balloons had inside diameters of about .025 inches and wall thicknesses of about .0065 inches.

The balloons were tested according to the procedure described above for Examples 1-180, except that outside diameters were measured at 1 atm increments from 4-16 atms, and then the balloons were burst.

Tables 22-28 below list certain parameters (PEBAX grade, dimensions, cone angle, rated burst, and hold time representing the total amount of time that the mold was held in the water). The tables also show results of the testing of the expander members.

Table 22

## BALLOON COMPLIANCE

|                           |             |
|---------------------------|-------------|
| PEBAX Grade:              | 7233        |
| Dimensions (dia. x lgt.): | 3.0 x 20 mm |
| Cone Angle:               | 10 degrees  |
| Rated Burst:              | 176 psi     |
| Hold (Secs.)              | 15          |

| Pressure             |       | DIAMETER (inches) |       |       |       |       |  |
|----------------------|-------|-------------------|-------|-------|-------|-------|--|
|                      |       | Balloon Number    |       |       |       |       |  |
| atm                  | psi   | 207               | 208   | 209   | 210   | 211   |  |
| 4                    | 58.8  | .111              | .111  | .112  | .112  | .112  |  |
| 5                    | 73.5  | .113              | .114  | .115  | .114  | .115  |  |
| 6                    | 88.2  | .116              | .116  | .117  | .116  | .117  |  |
| 7                    | 102.5 | .118              | .117  | .118  | .117  | .118  |  |
| 8                    | 117.6 | .119              | .119  | .119  | .118  | .119  |  |
| 9                    | 132.3 | .120              | .120  | .120  | .119  | .120  |  |
| 10                   | 147.0 | .122              | .121  | .121  | .120  | .121  |  |
| 11                   | 161.7 | .122              | .122  | .122  | .121  | .122  |  |
| 12                   | 176.4 | .123              | .123  | .123  | .122  | .123  |  |
| 13                   | 191.1 | .124              | .124  | .124  | .123  | .124  |  |
| 14                   | 205.8 | .125              | .125  | .125  | .124  | .125  |  |
| 15                   | 220.5 | .126              | .126  | .125  | .125  | .126  |  |
| 16                   | 235.2 | .127              | .127  | .126  | .125  | .127  |  |
|                      |       |                   |       |       |       |       |  |
| Burst Pressure (psi) |       | 278               | 249   | 278   | 307   | 291   |  |
| Direction of Burst   |       | Axial             | Axial | Axial | Axial | Axial |  |

Table 23

## BALLOON COMPLIANCE

|                           |             |
|---------------------------|-------------|
| PEBAX Grade:              | 7233        |
| Dimensions (dia. x lgt.): | 3.0 x 20 mm |
| Cone Angle:               | 10 degrees  |
| Rated Burst:              | 176 psi     |
| Hold (Secs.)              | 15          |

| Pressure             |       |       | DIAMETER (inches) |       |       |       |       |  |  |
|----------------------|-------|-------|-------------------|-------|-------|-------|-------|--|--|
|                      |       |       | Balloon Number    |       |       |       |       |  |  |
| atm                  | psi   | 212   | 213               | 214   | 215   | 216   |       |  |  |
| 4                    | 58.8  | .113  | .113              | .111  | .112  | .111  |       |  |  |
| 5                    | 73.5  | .115  | .115              | .114  | .114  | .114  |       |  |  |
| 6                    | 88.2  | .117  | .117              | .116  | .116  | .116  |       |  |  |
| 7                    | 102.5 | .118  | .118              | .118  | .118  | .117  |       |  |  |
| 8                    | 117.6 | .119  | .119              | .119  | .119  | .118  |       |  |  |
| 9                    | 132.3 | .120  | .120              | .120  | .120  | .120  |       |  |  |
| 10                   | 147.0 | .121  | .121              | .121  | .121  | .120  |       |  |  |
| 11                   | 161.7 | .122  | .122              | .122  | .122  | .121  |       |  |  |
| 12                   | 176.4 | .123  | .123              | .123  | .123  | .122  |       |  |  |
| 13                   | 191.1 | .124  | .124              | .124  | .124  | .123  |       |  |  |
| 14                   | 205.8 | .125  | .125              | .125  | .125  | .124  |       |  |  |
| 15                   | 220.5 | .126  | .126              | .126  | .126  | .125  |       |  |  |
| 16                   | 235.2 | .127  | .127              | .127  | .127  | .126  |       |  |  |
|                      |       |       |                   |       |       |       |       |  |  |
| Burst Pressure (psi) |       | 266   | 264               | 280   | 290   | 280   |       |  |  |
| Direction of Burst   |       | Axial | Axial             | Axial | Axial | Axial | Axial |  |  |

Table 24

**BALLOON COMPLIANCE**

PEBAX Grade: 7233  
 Dimensions (dia. x lgt.): 3.0 x 20 mm  
 Cone Angle: 10 degrees  
 Rated Burst: 176 psi  
 Hold (Secs.) 15

| Pressure             |       | DIAMETER (inches) |       |       |       |       |       |
|----------------------|-------|-------------------|-------|-------|-------|-------|-------|
|                      |       | Balloon Number    |       |       |       |       |       |
| atm                  | psi   | 217               | 218   | 219   | 220   | 221   |       |
| 4                    | 58.8  | .109              | .110  | .110  | .109  | .109  |       |
| 5                    | 73.5  | .112              | .114  | .114  | .112  | .114  |       |
| 6                    | 88.2  | .114              | .116  | .115  | .114  | .116  |       |
| 7                    | 102.5 | .116              | .117  | .117  | .116  | .118  |       |
| 8                    | 117.6 | .117              | .119  | .118  | .117  | .119  |       |
| 9                    | 132.3 | .119              | .119  | .120  | .119  | .120  |       |
| 10                   | 147.0 | .120              | .120  | .121  | .120  | .121  |       |
| 11                   | 161.7 | .121              | .121  | .122  | .121  | .122  |       |
| 12                   | 176.4 | .122              | .122  | .123  | .122  | .123  |       |
| 13                   | 191.1 | .123              | .124  | .124  | .123  | .124  |       |
| 14                   | 205.8 | .124              | .125  | .125  | .124  | .125  |       |
| 15                   | 220.5 | .125              | .126  | .126  | .125  | .126  |       |
| 16                   | 235.2 | .125              | .127  | .127  | .126  | .127  |       |
| Burst Pressure (psi) |       | 290               | 250   | 250   | 250   | 250   | 250   |
| Direction of Burst   |       | Axial             | Axial | Axial | Axial | Axial | Axial |

Table 25  
BALLOON COMPLIANCE

PEBAX Grade: 7233  
 Dimensions (dia. x lgt.): 3.0 x 20 mm  
 Cone Angle: 10 degrees  
 Rated Burst: 176 psi  
 Hold (Secs.) 15

| Pressure             |       | DIAMETER (inches) |       |       |       |       |  |  |
|----------------------|-------|-------------------|-------|-------|-------|-------|--|--|
|                      |       | Balloon Number    |       |       |       |       |  |  |
| atm                  | psi   | 222               | 223   | 224   | 225   | 226   |  |  |
| 4                    | 58.8  | .108              | .111  | .111  | .111  | .110  |  |  |
| 5                    | 73.5  | .110              | .114  | .114  | .113  | .113  |  |  |
| 6                    | 88.2  | .112              | .116  | .116  | .115  | .115  |  |  |
| 7                    | 102.5 | .114              | .118  | .117  | .117  | .117  |  |  |
| 8                    | 117.6 | .116              | .119  | .118  | .118  | .118  |  |  |
| 9                    | 132.3 | .117              | .120  | .120  | .119  | .119  |  |  |
| 10                   | 147.0 | .119              | .121  | .121  | .120  | .120  |  |  |
| 11                   | 161.7 | .120              | .122  | .122  | .121  | .121  |  |  |
| 12                   | 176.4 | .121              | .123  | .123  | .122  | .122  |  |  |
| 13                   | 191.1 | .122              | .124  | .124  | .123  | .123  |  |  |
| 14                   | 205.8 | .123              | .125  | .125  | .124  | .124  |  |  |
| 15                   | 220.5 | .124              | .126  | .126  | .125  | .125  |  |  |
| 16                   | 235.2 | .125              | .127  | .127  | .126  | .126  |  |  |
| Burst Pressure (psi) |       | 264               | 280   | 260   | 280   | 290   |  |  |
| Direction of Burst   |       | Axial             | Axial | Axial | Axial | Axial |  |  |

Table 26

## BALLOON COMPLIANCE

|                           |             |
|---------------------------|-------------|
| PEBAX Grade:              | 7233        |
| Dimensions (dia. x lgt.): | 3.0 x 20 mm |
| Cone Angle:               | 10 degrees  |
| Rated Burst:              | 176 psi     |
| Hold (Secs.)              | 15          |

| Pressure             |       | DIAMETER (inches) |       |       |       |       |  |
|----------------------|-------|-------------------|-------|-------|-------|-------|--|
|                      |       | Balloon Number    |       |       |       |       |  |
|                      |       | 227               | 228   | 229   | 230   | 231   |  |
| atm                  | psi   | .111              | .111  | .110  | .111  | .110  |  |
| 4                    | 58.8  | .113              | .114  | .113  | .113  | .113  |  |
| 5                    | 73.5  | .115              | .116  | .114  | .115  | .115  |  |
| 6                    | 88.2  | .117              | .118  | .116  | .117  | .117  |  |
| 7                    | 102.5 | .119              | .119  | .118  | .118  | .118  |  |
| 8                    | 117.6 | .120              | .120  | .119  | .119  | .119  |  |
| 9                    | 132.3 | .121              | .121  | .120  | .120  | .120  |  |
| 10                   | 147.0 | .122              | .122  | .121  | .121  | .121  |  |
| 11                   | 161.7 | .123              | .123  | .123  | .122  | .122  |  |
| 12                   | 176.4 | .124              | .124  | .124  | .123  | .123  |  |
| 13                   | 191.1 | .124              | .125  | .125  | .124  | .124  |  |
| 14                   | 205.8 | .125              | .126  | .126  | .125  | .125  |  |
| 15                   | 220.5 | .126              | .127  | .127  | .126  | .126  |  |
| 16                   | 235.2 |                   |       |       |       |       |  |
| Burst Pressure (psi) |       | 278               | 280   | 265   | 260   | 260   |  |
| Direction of Burst   |       | Axial             | Axial | Axial | Axial | Axial |  |



Table 27

## BALLOON COMPLIANCE

PEBAX Grade: 7233  
 Dimensions (dia. x lgt.): 3.0 x 20 mm  
 Cone Angle: 10 degrees  
 Rated Burst: 176 psi  
 Hold (Secs.) 15

| Pressure             |       | DIAMETER (inches) |       |       |       |       |  |  |
|----------------------|-------|-------------------|-------|-------|-------|-------|--|--|
|                      |       | Balloon Number    |       |       |       |       |  |  |
| atm                  | psi   | 232               | 233   | 234   | 235   | 236   |  |  |
| 4                    | 58.8  | .111              | .111  | .110  | .111  | .112  |  |  |
| 5                    | 73.5  | .114              | .114  | .113  | .114  | .115  |  |  |
| 6                    | 88.2  | .116              | .116  | .116  | .116  | .1165 |  |  |
| 7                    | 102.5 | .117              | .117  | .117  | .117  | .118  |  |  |
| 8                    | 117.6 | .119              | .190  | .118  | .1185 | .119  |  |  |
| 9                    | 132.3 | .120              | .120  | .119  | .120  | .120  |  |  |
| 10                   | 147.0 | .121              | .121  | .1205 | .121  | .121  |  |  |
| 11                   | 161.7 | .122              | .122  | .122  | .122  | .122  |  |  |
| 12                   | 176.4 | .1225             | .123  | .123  | .123  | .123  |  |  |
| 13                   | 191.1 | .124              | .124  | .124  | .124  | .124  |  |  |
| 14                   | 205.8 | .124              | .125  | .125  | .125  | .125  |  |  |
| 15                   | 220.5 | .125              | .126  | .125  | .126  | .126  |  |  |
| 16                   | 235.2 | .126              | .127  | .126  | .127  | .127  |  |  |
| Burst Pressure (psi) |       | 265               | 280   | 305   | 278   | 260   |  |  |
| Direction of Burst   |       | Axial             | Axial | Axial | Axial | Axial |  |  |

Table 28  
BALLOON COMPLIANCE  
MEASUREMENTS BEFORE TESTING

|     | Double Wall Thickness Measurements |        |                  |
|-----|------------------------------------|--------|------------------|
|     | Proximal Side-Body                 | Center | Distal Side-Body |
| 207 | .00175                             | .00120 | .00135           |
| 208 | .00145                             | .00140 | .00120           |
| 209 | .00130                             | .00140 | .00140           |
| 210 | .00140                             | .00150 | .00140           |
| 211 | .00165                             | .00175 | .00185           |
| 212 | .00135                             | .00120 | .00125           |
| 213 | .00150                             | .00140 | .00120           |
| 214 | .00135                             | .00120 | .00115           |
| 215 | .00155                             | .00130 | .00120           |
| 216 | .00135                             | .00120 | .00125           |
| 217 | .00140                             | .00135 | .00145           |
| 218 | .00165                             | .00130 | .00125           |
| 219 | .00145                             | .00135 | .00130           |
| 220 | .00155                             | .00120 | .00140           |
| 221 | .00135                             | .00120 | .00120           |
| 222 | .00155                             | .00135 | .00140           |
| 223 | .00140                             | .00130 | .00135           |
| 224 | .00145                             | .00135 | .00120           |
| 225 | .00160                             | .00135 | .00125           |
| 226 | .00150                             | .00135 | .00130           |
| 227 | .00155                             | .00135 | .00135           |
| 228 | .00155                             | .00150 | .00135           |
| 229 | .00150                             | .00135 | .00130           |
| 230 | .00135                             | .00135 | .00120           |
| 231 | .00160                             | .00135 | .00130           |
| 232 | .00160                             | .00135 | .00130           |
| 233 | .00140                             | .00120 | .00120           |
| 234 | .00145                             | .00135 | .00125           |
| 235 | .00150                             | .00145 | .00120           |
| 236 | .00145                             | .00135 | .00125           |

Examples 237-266

30 balloons were made according to the procedure described above for Examples 1-180.

5 The balloons were tested according to the procedure described above for Examples 1-180, except that balloons were tested at 1 atm increments from 4-16 atm and then burst.

10 Tables 29-35 below list certain parameters (PEBAX grade, dimensions, cone angle, rated burst, and hold time representing the total amount of time that the mold was held in the water). The tables also show results of the testing of the expander members.









Table 33

## BALLOON COMPLIANCE

PEBAX Grade: 6333  
 Dimensions (dia. x lg.): 3.0 x 20 mm  
 Cone Angle: 10 degrees  
 Rated Burst: 176 psi  
 Hold (Secs.) 15

| Pressure             | DIAMETER (inches) |       |       |       |       |       |
|----------------------|-------------------|-------|-------|-------|-------|-------|
|                      | Balloon Number    |       |       |       |       |       |
| atm                  | 257               | 258   | 259   | 260   | 261   |       |
| 4                    | 58.8              | .115  | .115  | .114  | .114  | .115  |
| 5                    | 73.5              | .118  | .117  | .117  | .117  | .118  |
| 6                    | 88.2              | .120  | .119  | .119  | .118  | .120  |
| 7                    | 102.5             | .121  | .120  | .120  | .120  | .122  |
| 8                    | 117.6             | .123  | .121  | .121  | .122  | .123  |
| 9                    | 132.3             | .124  | .122  | .123  | .123  | .124  |
| 10                   | 147.0             | .125  | .123  | .124  | .125  | .125  |
| 11                   | 161.7             | .127  | .125  | .125  | .126  | .126  |
| 12                   | 176.4             | .128  | .127  | .127  | .128  | .128  |
| 13                   | 191.1             | .129  | .129  | .129  | .129  | .130  |
| 14                   | 205.8             | .131  | .131  | .130  | .131  | .132  |
| 15                   | 220.5             | .132  | .132  | .132  | .133  | .133  |
| 16                   | 235.2             | .134  | .134  | .134  | .135  | .134  |
|                      |                   |       |       |       |       |       |
| Burst Pressure (psi) | 250               | 235   | 250   | 250   | 260   |       |
| Direction of Burst   | Axial             | Axial | Axial | Axial | Axial | Axial |



Table 34

## BALLOON COMPLIANCE

PEBAX Grade: 6333  
 Dimensions (dia. x lgt.): 3.0 x 20 mm  
 Cone Angle: 10 degrees  
 Rated Burst: 176 psi  
 Hold (Secs.) 15

| Pressure             |       | DIAMETER (inches) |       |       |       |       |  |  |
|----------------------|-------|-------------------|-------|-------|-------|-------|--|--|
|                      |       | Balloon Number    |       |       |       |       |  |  |
| atm                  | psi   | 262               | 263   | 264   | 265   | 266   |  |  |
| 4                    | 58.8  | .115              | .114  | .114  | .115  | .115  |  |  |
| 5                    | 73.5  | .118              | .117  | .117  | .117  | .118  |  |  |
| 6                    | 88.2  | .119              | .119  | .118  | .119  | .120  |  |  |
| 7                    | 102.5 | .121              | .120  | .120  | .121  | .121  |  |  |
| 8                    | 117.6 | .122              | .121  | .121  | .122  | .122  |  |  |
| 9                    | 132.3 | .123              | .124  | .122  | .123  | .124  |  |  |
| 10                   | 147.0 | .124              | .125  | .123  | .124  | .125  |  |  |
| 11                   | 161.7 | .126              | .127  | .125  | .125  | .126  |  |  |
| 12                   | 176.4 | .128              | .128  | .127  | .127  | .128  |  |  |
| 13                   | 191.1 | .129              | .130  | .129  | .129  | .129  |  |  |
| 14                   | 205.8 | .131              | .131  | .130  | .130  | .131  |  |  |
| 15                   | 220.5 | .133              | .133  | .132  | .132  | .133  |  |  |
| 16                   | 235.2 | .134              | .135  | .134  | .135  | .135  |  |  |
| Burst Pressure (psi) |       | 250               | 250   | 268   | 250   | 250   |  |  |
| Direction of Burst   |       | Axial             | Axial | Axial | Axial | Axial |  |  |

Table 35  
BALLOON COMPLIANCE  
MEASUREMENTS BEFORE TESTING

|     | Double Wall Thickness Measurements |        |                  |
|-----|------------------------------------|--------|------------------|
|     | Proximal Side-Body                 | Center | Distal Side-Body |
| 237 | .00155                             | .00130 | .00120           |
| 238 | .00135                             | .00120 | .00120           |
| 239 | .00125                             | .00120 | .00110           |
| 240 | .00125                             | .00120 | .00120           |
| 241 | .00130                             | .00120 | .00120           |
| 242 | .00135                             | .00120 | .00110           |
| 243 | .00130                             | .00115 | .00120           |
| 244 | .00130                             | .00120 | .00110           |
| 245 | .00135                             | .00125 | .00110           |
| 246 | .00135                             | .00120 | .00120           |
| 247 | .00135                             | .00120 | .00115           |
| 248 | .00125                             | .00120 | .00115           |
| 249 | .00120                             | .00120 | .00110           |
| 250 | .00130                             | .00125 | .00110           |
| 251 | .00130                             | .00120 | .00115           |
| 252 | .00135                             | .00120 | .00105           |
| 253 | .00130                             | .00120 | .00110           |
| 254 | .00120                             | .00110 | .00110           |
| 255 | .00120                             | .00115 | .00105           |
| 256 | .00125                             | .00120 | .00110           |
| 257 | .00125                             | .00120 | .00110           |
| 258 | .00135                             | .00120 | .00110           |
| 259 | .00135                             | .00120 | .00115           |
| 260 | .00120                             | .00110 | .00110           |
| 261 | .00130                             | .00125 | .00120           |
| 262 | .00130                             | .00120 | .00110           |
| 263 | .00125                             | .00120 | .00115           |
| 264 | .00130                             | .00115 | .00115           |
| 265 | .00135                             | .00120 | .00110           |
| 266 | .00120                             | .00110 | .00105           |

Examples 267-276

10 balloons were made according to the procedure described above for Examples 1-180, except that balloons had inside diameters of about .025 inches and wall  
5 thicknesses of about .0065 inches.

The balloons were tested according to the procedure described above for Examples 1-180, except that outside diameters were measured at 1 atm increments from 4-16 atms, and then the balloons were burst.

10 Tables 36-38 below list certain parameters (PEBAX grade, dimensions, cone angle, rated burst, and hold time representing the total amount of time that the mold was held in the water). The tables also show results of the testing of the expander members.

15

Table 36

## BALLOON COMPLIANCE

|                           |             |
|---------------------------|-------------|
| PEBAX Grade:              | 7033        |
| Dimensions (dia. x lgt.): | 3.0 x 20 mm |
| Cone Angle:               | 10 degrees  |
| Rated Burst:              | 176 psi     |
| Hold (Secs.)              | 15          |

| Pressure             |       | DIAMETER (inches) |       |       |       |       |
|----------------------|-------|-------------------|-------|-------|-------|-------|
|                      |       | Balloon Number    |       |       |       |       |
|                      |       | 267               | 268   | 269   | 270   | 271   |
| atm                  | psi   |                   |       |       |       |       |
| 4                    | 58.8  | .112              | .113  | .113  | .113  | .113  |
| 5                    | 73.5  | .116              | .116  | .116  | .116  | .116  |
| 6                    | 88.2  | .118              | .118  | .118  | .118  | .118  |
| 7                    | 102.5 | .120              | .119  | .120  | .119  | .119  |
| 8                    | 117.6 | .121              | .120  | .121  | .120  | .120  |
| 9                    | 132.3 | .122              | .121  | .122  | .121  | .121  |
| 10                   | 147.0 | .123              | .122  | .124  | .122  | .123  |
| 11                   | 161.7 | .124              | .123  | .125  | .124  | .124  |
| 12                   | 176.4 | .125              | .125  | .126  | .124  | .125  |
| 13                   | 191.1 | .126              | .127  | .127  | .125  | .126  |
| 14                   | 205.8 | .127              | .1275 | .128  | .127  | .127  |
| 15                   | 220.5 | .128              | .128  | .129  | .1275 | .128  |
| 16                   | 235.2 | .129              | .129  | .130  | .1285 | .129  |
|                      |       |                   |       |       |       |       |
| Burst Pressure (psi) |       | 263               | 264   | 250   | 264   | 250   |
| Direction of Burst   |       | Axial             | Axial | Axial | Axial | Axial |

Table 37

## BALLOON COMPLIANCE

|                           |             |
|---------------------------|-------------|
| PEBAX Grade:              | 7033        |
| Dimensions (dia. x lgt.): | 3.0 x 20 mm |
| Cone Angle:               | 10 degrees  |
| Rated Burst:              | 176 psi     |
| Hold (Secs.)              | 15          |

| Pressure             |       | DIAMETER (inches) |       |       |       |       |  |
|----------------------|-------|-------------------|-------|-------|-------|-------|--|
|                      |       | Balloon Number    |       |       |       |       |  |
|                      |       | 272               | 273   | 274   | 275   | 276   |  |
| atm                  | psi   |                   |       |       |       |       |  |
| 4                    | 58.8  | .112              | .114  | .114  | .114  | .113  |  |
| 5                    | 73.5  | .115              | .117  | .116  | .117  | .116  |  |
| 6                    | 88.2  | .117              | .118  | .117  | .118  | .118  |  |
| 7                    | 102.5 | .1185             | .120  | .119  | .120  | .120  |  |
| 8                    | 117.6 | .121              | .121  | .120  | .121  | .122  |  |
| 9                    | 132.3 | .122              | .122  | .121  | .122  | .122  |  |
| 10                   | 147.0 | .123              | .123  | .123  | .123  | .123  |  |
| 11                   | 161.7 | .124              | .124  | .124  | .124  | .124  |  |
| 12                   | 176.4 | .126              | .126  | .125  | .125  | .125  |  |
| 13                   | 191.1 | .128              | .1265 | .127  | .126  | .126  |  |
| 14                   | 205.8 | .128              | .1280 | .128  | .127  | .127  |  |
| 15                   | 220.5 | .129              | .129  | .1295 | .128  | .128  |  |
| 16                   | 235.2 | .130              | .130  | .131  | .129  | .129  |  |
|                      |       |                   |       |       |       |       |  |
| Burst Pressure (psi) |       | 250               | 264   | 264   | 250   | 264   |  |
| Direction of Burst   |       | Axial             | Axial | Axial | Axial | Axial |  |

Table 38

## BALLOON COMPLIANCE MEASUREMENTS BEFORE TESTING

[illegible]

Examples 277-306

30 balloons were made according to the procedure described above for Examples 1-180, except that cone angles were 267 and the parison inside diameter was .025  
5 inches with a wall thickness of .0065.

The balloons were tested according to the procedure described above for Examples 1-180, except that outside diameters were measured at 1 atm increments from 4-16  
atms, and then the balloons were burst.

10 Tables 39-41 below list certain parameters (PEBAX grade, dimensions, cone angle, rated burst, and hold time representing the total amount of time that the mold was held in the water). The tables also show results of the testing of the expander members.

Table 39

## BALLOON COMPLIANCE

PEBAX Grade: 7033  
 Dimensions (dia. x lgt.): 3.0 x 20 mm  
 Cone Angle: 26°  
 Rated Burst: 176  
 Hold (Secs.) 15

| Pressure<br>atm | DIAMETER (cm)   |        |        |        |         |        |        |        |        |        |  |  |  |  |  |  |
|-----------------|-----------------|--------|--------|--------|---------|--------|--------|--------|--------|--------|--|--|--|--|--|--|
|                 | Balloon Numbers |        |        |        |         |        |        |        |        |        |  |  |  |  |  |  |
|                 | 277             | 278    | 279    | 280    | 281     | 282    | 283    | 284    | 285    | 286    |  |  |  |  |  |  |
| 4               | 2.9972          | 3.0226 | 2.9718 | 2.9210 | 2.9210  | 2.9210 | 2.8448 | 2.8194 | 2.8956 | 2.9210 |  |  |  |  |  |  |
| 5               | 3.0988          | 3.1242 | 3.0988 | 3.0226 | 2.9972  | 2.9972 | 2.9972 | 2.9972 | 3.0226 | 3.0480 |  |  |  |  |  |  |
| 6               | 3.1496          | 3.1750 | 3.1496 | 3.1242 | 3.07340 | 3.1496 | 3.0988 | 3.0988 | 3.1750 | 3.1496 |  |  |  |  |  |  |
| 7               | 3.2004          | 3.2258 | 3.2004 | 3.1750 | 3.1750  | 3.2258 | 3.2004 | 3.2004 | 3.2258 | 3.2004 |  |  |  |  |  |  |
| 8               | 3.2766          | 3.2512 | 3.2258 | 3.2258 | 3.2258  | 3.2766 | 3.2512 | 3.2512 | 3.2766 | 3.3020 |  |  |  |  |  |  |
| 9               | 3.3020          | 3.3020 | 3.2766 | 3.2766 | 3.2766  | 3.3528 | 3.3020 | 3.3020 | 3.3274 | 3.3528 |  |  |  |  |  |  |
| 10              | 3.3528          | 3.3528 | 3.3274 | 3.3030 | 3.3274  | 3.4036 | 3.3528 | 3.3528 | 3.4036 | 3.4036 |  |  |  |  |  |  |
| 11              | 3.3782          | 3.4036 | 3.3782 | 3.3528 | 3.3782  | 3.4544 | 3.4036 | 3.4036 | 3.4544 | 3.4544 |  |  |  |  |  |  |
| 12              | 3.4544          | 3.4544 | 3.4290 | 3.4036 | 3.4036  | 3.5052 | 3.4544 | 3.4544 | 3.5052 | 3.5306 |  |  |  |  |  |  |
| 13              | 3.5052          | 3.4798 | 3.5052 | 3.4290 | 3.4544  | 3.5814 | 3.5052 | 3.5052 | 3.5814 | 3.6068 |  |  |  |  |  |  |
| 14              | 3.5560          | 3.5560 | 3.5814 | 3.5052 | 3.5052  | 3.6576 | 3.5560 | 3.5560 | 3.6576 | 3.6576 |  |  |  |  |  |  |
| 15              | 3.5814          | 3.6068 | 3.6068 | 3.5306 | 3.5306  | 3.7338 | 3.6068 | 3.6322 | 3.8100 | 3.7592 |  |  |  |  |  |  |
| 16              | 3.6576          | 3.6830 | 3.6322 | 3.6068 | 3.6068  | 3.8608 | 3.6576 | 3.6576 | 3.8100 | 3.8100 |  |  |  |  |  |  |
| Burst psi       | 290             | 265    | 265    | 295    | 260     | 265    | 265    | 260    | 250    | 265    |  |  |  |  |  |  |
| atm             | 19.70           | 18.02  | 18.02  | 20.06  | 17.68   | 18.02  | 18.02  | 17.68  | 17.00  | 18.02  |  |  |  |  |  |  |



Table 40

## BALLOON COMPLIANCE

PEBAX Grade: 7033  
 Dimensions (dia. x lgt.): 3.0 x 20 mm  
 Cone Angle: 26°  
 Rated Burst: 176  
 Hold (Secs.) 15

| Pressure  | DIAMETER (cm)   |        |        |        |        |        |        |        |        |        |  |  |  |  |  |  |
|-----------|-----------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--|--|--|--|--|--|
|           | Balloon Numbers |        |        |        |        |        |        |        |        |        |  |  |  |  |  |  |
| atm       | 287             | 288    | 289    | 290    | 291    | 292    | 293    | 294    | 295    | 296    |  |  |  |  |  |  |
| 4         | 2.8956          | 2.8956 | 2.9210 | 2.8702 | 2.8956 | 2.9718 | 2.8956 | 2.9464 | 2.9210 | 2.8702 |  |  |  |  |  |  |
| 5         | 2.9972          | 2.9972 | 3.0480 | 2.9972 | 3.0226 | 3.0988 | 3.0226 | 3.0734 | 3.0480 | 2.9718 |  |  |  |  |  |  |
| 6         | 3.1242          | 3.0988 | 3.1496 | 3.0988 | 3.1242 | 3.1750 | 3.1242 | 3.1750 | 3.1242 | 3.0734 |  |  |  |  |  |  |
| 7         | 3.2004          | 3.2004 | 3.2258 | 3.1496 | 3.1750 | 3.2512 | 3.1750 | 3.2258 | 3.2004 | 3.1750 |  |  |  |  |  |  |
| 8         | 3.2512          | 3.2258 | 3.3020 | 3.2258 | 3.2512 | 3.3020 | 3.2258 | 3.2766 | 3.2512 | 3.2258 |  |  |  |  |  |  |
| 9         | 3.3274          | 3.3020 | 3.3528 | 3.2766 | 3.3020 | 3.3528 | 3.2766 | 3.3274 | 3.3274 | 3.2766 |  |  |  |  |  |  |
| 10        | 3.3782          | 3.3528 | 3.4036 | 3.3274 | 3.3528 | 3.4036 | 3.3274 | 3.3782 | 3.3782 | 3.3274 |  |  |  |  |  |  |
| 11        | 3.4290          | 3.4036 | 3.4798 | 3.3782 | 3.4036 | 3.4544 | 3.3782 | 3.4290 | 3.4290 | 3.3782 |  |  |  |  |  |  |
| 12        | 3.4798          | 3.4544 | 3.5560 | 3.4290 | 3.4544 | 3.5052 | 3.4290 | 3.5052 | 3.4798 | 3.4290 |  |  |  |  |  |  |
| 13        | 3.5560          | 3.5306 | 3.6068 | 3.4798 | 3.5052 | 3.5306 | 3.4544 | 3.5560 | 3.5560 | 3.4798 |  |  |  |  |  |  |
| 14        | 3.6068          | 3.5560 | 3.6576 | 3.5306 | 3.5560 | 3.5306 | 3.5052 | 3.6068 | 3.6068 | 3.5052 |  |  |  |  |  |  |
| 15        | 3.6576          | 3.6068 | 3.7338 | 3.5814 | 3.6322 | 3.5306 | 3.5306 | 3.6830 | 3.6830 | 3.5814 |  |  |  |  |  |  |
| 16        | 3.7592          | 3.6576 | 3.8354 | 3.6576 | 3.7084 | 3.5560 | 3.5560 | 3.7592 | 3.6830 | 3.6322 |  |  |  |  |  |  |
| Burst psi | 265             | 265    | 265    | 265    | 265    | 265    | 265    | 260    | 250    | 265    |  |  |  |  |  |  |
| atm       | 18.02           | 18.02  | 18.02  | 18.02  | 18.02  | 18.02  | 18.02  | 17.68  | 17.00  | 18.02  |  |  |  |  |  |  |

Table 41

## BALLOON COMPLIANCE

PEBAX Grade: 7033  
 Dimensions (dia. x lgt.): 3.0 x 20 mm  
 Cone Angle: 26°  
 Rated Burst: 176  
 Hold (Secs.) 15

| Pressure<br>atm | DIAMETER (cm)   |        |        |        |        |        |        |        |        |        |  |  |  |  |  |  |
|-----------------|-----------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--|--|--|--|--|--|
|                 | Balloon Numbers |        |        |        |        |        |        |        |        |        |  |  |  |  |  |  |
| 4               | 297             | 298    | 299    | 300    | 301    | 302    | 303    | 304    | 305    | 306    |  |  |  |  |  |  |
| 5               | 2.8702          | 2.8956 | 2.8194 | 2.8194 | 2.8702 | 2.7940 | 2.8448 | 2.8702 | 2.8956 | 2.8448 |  |  |  |  |  |  |
| 6               | 2.9972          | 2.9972 | 2.9972 | 2.9210 | 2.9972 | 2.9972 | 2.9972 | 2.9718 | 2.9972 | 2.9972 |  |  |  |  |  |  |
| 7               | 3.1242          | 3.1242 | 3.0988 | 3.0480 | 3.0988 | 3.1242 | 3.0988 | 3.0734 | 3.0988 | 3.0988 |  |  |  |  |  |  |
| 8               | 3.1750          | 3.1750 | 3.2004 | 3.1496 | 3.1750 | 3.2004 | 3.1750 | 3.1496 | 3.1750 | 3.2004 |  |  |  |  |  |  |
| 9               | 3.2512          | 3.2512 | 3.2512 | 3.2004 | 3.2258 | 3.2512 | 3.2512 | 3.2004 | 3.2258 | 3.2766 |  |  |  |  |  |  |
| 10              | 3.3274          | 3.3020 | 3.2766 | 3.2512 | 3.3020 | 3.3274 | 3.3020 | 3.2512 | 3.2766 | 3.3274 |  |  |  |  |  |  |
| 11              | 3.3782          | 3.3528 | 3.3274 | 3.3782 | 3.3528 | 3.4036 | 3.3274 | 3.3020 | 3.3274 | 3.4036 |  |  |  |  |  |  |
| 12              | 3.4544          | 3.4036 | 3.3782 | 3.4036 | 3.4544 | 3.4544 | 3.3782 | 3.3782 | 3.3782 | 3.4544 |  |  |  |  |  |  |
| 13              | 3.5052          | 3.4798 | 3.4555 | 3.4036 | 3.4544 | 3.5052 | 3.4544 | 3.4290 | 3.4290 | 3.5052 |  |  |  |  |  |  |
| 14              | 3.5560          | 3.5052 | 3.5306 | 3.4544 | 3.5052 | 3.6068 | 3.5052 | 3.4544 | 3.4798 | 3.5814 |  |  |  |  |  |  |
| 15              | 3.6322          | 3.5306 | 3.5814 | 3.5052 | 3.5560 | 3.6576 | 3.5560 | 3.5052 | 3.5306 | 3.6322 |  |  |  |  |  |  |
| 16              | 3.6830          | 3.5814 | 3.6322 | 3.5560 | 3.6322 | 3.7592 | 3.6068 | 3.5560 | 3.5814 | 3.7084 |  |  |  |  |  |  |
| Burst psi       | 3.7846          | 3.6322 | 3.7084 | 3.6322 | 3.6830 | 3.8100 | 3.6830 | 3.6322 | 3.6322 | 3.7846 |  |  |  |  |  |  |
| atm             | 265             | 260    | 265    | 265    | 265    | 265    | 265    | 265    | 265    | 265    |  |  |  |  |  |  |
|                 | 18.02           | 17.68  | 18.02  | 18.02  | 18.02  | 18.02  | 18.02  | 18.02  | 18.02  | 18.02  |  |  |  |  |  |  |

Examples 307-366

60 balloons were made according to the following procedure: Tubing was placed into a mold and preheated for 15-30 seconds to a preselected balloon blowing temperature. The tubing was stretched and inflated to make a balloon. The balloon was allowed to remain at the balloon blowing temperature for 15-30 seconds, and then elevated to at least the crystallization temperature for 10-20 seconds. The balloon was then cooled to room temperature and removed from the mold.

The balloons were tested according to the procedure described above for Examples 1-180.

Tables 42-47 below list certain parameters (PEBAX grade, dimensions, crystallization temperature, mold temperature, left and right stretch dimensions, nitrogen pressure, and air flow). The tables also show results of the testing of the expander members.



Table 43

**PEBAX GRADE: 6333**

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS: CRYSTALIZATION: 260° F 190° F  
 TEMP: MOLD: 2.75 INCHES 2.75 INCHES  
 STRETCH: LEFT: 350 RIGHT:  
 PSI: 200  
 AIRFLOW:

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter: 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|---------------------------|---------------------------|---------------------------|----------------------|
| 317         | 0.00130                              | 0.00135                                 | 0.00130                               | .020x.035               | 0.116                     | 0.127                     | 0.135                     | 240                  |
| 318         | 0.00135                              | 0.00140                                 | 0.00140                               | .020x.035               | 0.114                     | 0.127                     | 0.135                     | 248                  |
| 319         | 0.00135                              | 0.00145                                 | 0.00135                               | .020x.035               | 0.116                     | 0.127                     | 0.134                     | 240                  |
| 320         | 0.00135                              | 0.00135                                 | 0.00145                               | .020x.035               | 0.115                     | 0.127                     | 0.134                     | 251                  |
| 321         | 0.00130                              | 0.00145                                 | 0.00130                               | .020x.035               | 0.115                     | 0.127                     | 0.135                     | 240                  |
| 322         | 0.00145                              | 0.00135                                 | 0.00135                               | .020x.035               |                           |                           |                           | 240                  |
| 323         | 0.00140                              | 0.00140                                 | 0.00140                               | .020x.035               |                           |                           |                           | 248                  |
| 324         | 0.00135                              | 0.00135                                 | 0.00140                               | .020x.035               |                           |                           |                           | 240                  |
| 325         | 0.00135                              | 0.00135                                 | 0.00135                               | .020x.035               |                           |                           |                           | 240                  |
| 326         | 0.00135                              | 0.00135                                 | 0.00135                               | .020x.035               |                           |                           |                           | 240                  |
| Average     | 0.001355                             | 0.00138                                 | 0.00137                               | .020x.035               | 0.1152                    | 0.127                     | 0.1346                    | 242.7                |
| Standard    | 4.38E-05                             | 4.216E-05                               | 4.74342E-05                           |                         | 0.000837                  | 1.86E-09                  | 0.000548                  | 4.423423             |

Calculated K-stat (psi): 219.6849  
 Calculated Hoop Stress (psi): 22747.53

Table 44

## PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 2 x 30 mm

PARAMETERS: CRYSTALIZATION: 200° F MOLD: 190° F  
 TEMP: LEFT: 2.75 INCHES RIGHT: 2.75 INCHES  
 STRETCH: 380  
 PSI: 200  
 AIRFLOW:

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 327         | 0.00130                              | 0.001350                                | 0.00130                               | .020x.035               | 0.115                    | 0.125                     | 0.129                     | 270                  |
| 328         | 0.00125                              | 0.001300                                | 0.00130                               | .020x.035               | 0.116                    | 0.125                     | 0.129                     | 270                  |
| 329         | 0.00130                              | 0.001350                                | 0.00130                               | .020x.035               | 0.116                    | 0.125                     | 0.132                     | 270                  |
| 330         | 0.00130                              | 0.001300                                | 0.00125                               | .020x.035               | 0.115                    | 0.127                     | 0.132                     | 263                  |
| 331         | 0.00125                              | 0.001300                                | 0.00130                               | .020x.035               | 0.116                    | 0.126                     | 0.132                     | 270                  |
| 332         | 0.00135                              | 0.001350                                | 0.00130                               | .020x.035               |                          |                           |                           | 280                  |
| 333         | 0.00135                              | 0.001300                                | 0.00130                               | .020x.035               |                          |                           |                           | 280                  |
| 334         | 0.00130                              | 0.001300                                | 0.00130                               | .020x.035               |                          |                           |                           | 270                  |
| 335         | 0.00125                              | 0.001250                                | 0.00120                               | .020x.035               |                          |                           |                           | 283                  |
| 336         | 0.00130                              | 0.001200                                | 0.00130                               | .020x.035               |                          |                           |                           | 240                  |
| Average     | 0.001295                             | 0.0013                                  | 1.285E-03                             | .020x.035               | 0.1156                   | 0.1256                    | 0.1308                    | 269.6                |
| Standard    | 3.69E-05                             | 4.714E-05                               | 3.37474E-05                           |                         | 0.000548                 | 0.000894                  | 0.001643                  | 12.09408             |

Calculated K-stat (psi): 206.6745  
 Calculated Hoop Stress (psi): 26148.08

Table 45

**PEBAX GRADE: 7033**

BALLOON DIMENSIONS (diameter x length): 3 x 30 mm

PARAMETERS:

|          |                 |             |        |             |
|----------|-----------------|-------------|--------|-------------|
| TEMP:    | CRYSTALIZATION: | 260° F      | MOLD:  | 210° F      |
| STRETCH: | LEFT:           | 2.25 INCHES | RIGHT: | 2.25 INCHES |
| PSI:     |                 | 320         |        |             |
| AIRFLOW: |                 | 200         |        |             |

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 337         | 0.00100                              | 0.00100                                 | 0.00100                               | .020x.035               | 0.121                    | 0.13                      | 0.138                     | 238                  |
| 338         | 0.00115                              | 0.00120                                 | 0.00100                               | .020x.035               | 0.121                    | 0.129                     | 0.136                     | 230                  |
| 339         | 0.00100                              | 0.00105                                 | 0.00115                               | .020x.035               | 0.121                    | 0.13                      | 0.138                     | 220                  |
| 340         | 0.00110                              | 0.00115                                 | 0.00100                               | .020x.035               | 0.121                    | 0.129                     | 0.136                     | 219                  |
| 341         | 0.00105                              | 0.00110                                 | 0.00100                               | .020x.035               | 0.121                    | 0.129                     | 0.137                     | 238                  |
| 342         | 0.00105                              | 0.00100                                 | 0.00100                               | .020x.035               |                          |                           |                           | 239                  |
| 343         | 0.00120                              | 0.00120                                 | 0.00105                               | .020x.035               |                          |                           |                           | 238                  |
| 344         | 0.00100                              | 0.00110                                 | 0.00105                               | .020x.035               |                          |                           |                           | 238                  |
| 345         | 0.00100                              | 0.00105                                 | 0.00105                               | .020x.035               |                          |                           |                           | 220                  |
| 346         | 0.00105                              | 0.00110                                 | 0.00100                               | .020x.035               |                          |                           |                           | 239                  |
| Average     | 0.00106                              | 0.001095                                | 0.00103                               | .020x.035               | 0.121                    | 0.1294                    | 0.137                     | 231.9                |
| Standard    | 6.99E-05                             | 7.246E-05                               | 4.83046E-05                           |                         | 0                        | 0.000548                  | 0.001                     | 8.83742              |

Calculated K-stat (psi): 185.9189  
 Calculated Hoop Stress (psi): 28309.3

Table 46

## PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS: TEMP: 190° F  
 STRETCH: 2 INCHES  
 PSI: 400  
 AIRFLOW: 200

CRYSTALLIZATION: 400° F  
 LEFT: 2 INCHES  
 RIGHT: 2 INCHES

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 347         | 0.00140                              | 0.00140                                 | 0.00140                               | .020x.035               | 0.113                    | 0.119                     | 0.124                     | 305                  |
| 348         | 0.00145                              | 0.00150                                 | 0.00145                               | .020x.035               | 0.111                    | 0.119                     | 0.124                     | 330                  |
| 349         | 0.00145                              | 0.00150                                 | 0.00150                               | .020x.035               | 0.113                    | 0.122                     | 0.124                     | 315                  |
| 350         | 0.00140                              | 0.00140                                 | 0.00140                               | .020x.035               | 0.115                    | 0.122                     | 0.125                     | 313                  |
| 351         | 0.00150                              | 0.00145                                 | 0.00140                               | .020x.035               | 0.113                    | 0.120                     | 0.124                     | 343                  |
| 352         | 0.00145                              | 0.00145                                 | 0.00135                               | .020x.035               |                          |                           |                           | 343                  |
| 353         | 0.00150                              | 0.00150                                 | 0.00140                               | .020x.035               |                          |                           |                           | 329                  |
| 354         | 0.00140                              | 0.00150                                 | 0.00140                               | .020x.035               |                          |                           |                           | 303                  |
| 355         | 0.00140                              | 0.00140                                 | 0.00140                               | .020x.035               |                          |                           |                           | 313                  |
| 356         | 0.00140                              | 0.00150                                 | 0.00140                               | .020x.035               |                          |                           |                           | 330                  |
| Average     | 0.001433                             | 0.00146                                 | 0.00141                               | .020x.035               | 0.113                    | 0.1204                    | 0.1242                    | 322.4                |
| Standard    | 4.33E-05                             | 4.595E-05                               | 3.94405E-05                           |                         | 0.001414                 | 0.001517                  | 0.000447                  | 14.59985             |

Calculated K-stat (psi):

246.437

Calculated Hoop Stress (psi):

27081.6



Table 47

## PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

|          |                 |             |        |             |
|----------|-----------------|-------------|--------|-------------|
| TEMP:    | CRYSTALIZATION: | 260° F      | MOLD:  | 210° F      |
| STRETCH: | LEFT:           | 2.25 INCHES | RIGHT: | 2.25 INCHES |
| PSI:     |                 | 330         |        |             |
| AIRFLOW: |                 | 200         |        |             |

| Balloon No. | Double Centerwall Thickness (inches) | Double Proximal Wall Thickness (inches) | Double Distal Wall Thickness (inches) | Measured ID/OD (inches) | Diameter 50 psi (inches) | Diameter 100 psi (inches) | Diameter 150 psi (inches) | Burst Pressure (psi) |
|-------------|--------------------------------------|---|---------------------------------------|-------------------------|--------------------------|---------------------------|---------------------------|----------------------|
| 357         | 0.00110                              | 0.00100                                 | 0.00125                               | .020x.035               | 0.118                    | 0.125                     | 0.128                     | 240                  |
| 358         | 0.00100                              | 0.00105                                 | 0.00115                               | .020x.035               | 0.119                    | 0.125                     | 0.13                      | 260                  |
| 359         | 0.00100                              | 0.00105                                 | 0.00120                               | .020x.035               | 0.118                    | 0.123                     | 0.128                     | 242                  |
| 360         | 0.00110                              | 0.00120                                 | 0.00100                               | .020x.035               | 0.119                    | 0.126                     | 0.131                     | 245                  |
| 361         | 0.00110                              | 0.00120                                 | 0.00120                               | .020x.035               | 0.119                    | 0.125                     | 0.13                      | 260                  |
| 362         | 0.00100                              | 0.00100                                 | 0.00120                               | .020x.035               |                          |                           |                           | 260                  |
| 363         | 0.00120                              | 0.00120                                 | 0.00130                               | .020x.035               |                          |                           |                           | 242                  |
| 364         | 0.00115                              | 0.00105                                 | 0.00120                               | .020x.035               |                          |                           |                           | 262                  |
| 365         | 0.00100                              | 0.00105                                 | 0.00120                               | .020x.035               |                          |                           |                           | 260                  |
| 366         | 0.00110                              | 0.00100                                 | 0.00115                               | .020x.035               |                          |                           |                           | 231                  |
| Average     | 0.001075                             | 0.00108                                 | 0.001185                              | .020x.035               | 0.1186                   | 0.1248                    | 0.1294                    | 250.2                |
| Standard    | 7.17E-05                             | 8.5635E-05                              | 7.8351E-05                            |                         | 0.000548                 | 0.001095                  | 0.001342                  | 11.34117             |

Calculated K-stat (psi):

191.192

Calculated Hoop Stress (psi):

29046.47

Figures 4-15 were prepared by collecting data according to material type, and reducing the data to a series of quadratic equations that include stretch, crystallization temperature, and balloon blowing temperature as dependant variables. The equations were then plotted using a statistical design of experiments program called ECHIP<sup>®</sup>. Response variables of interest were then plotted.

With regard to Figures 4-15, the balloons were expanded to two times their original length in the axial direction.

The foregoing specification and figures are presented for the purpose of illustrating, and not limiting, the present invention.

CLAIMS

1. A balloon for an angioplasty device having a single polymeric layer comprising (a) from about 20 to about 100 weight percent polyesteretheramide copolymer,  
5 and (b) from about 0 to about 80 weight percent polyamide; wherein the polymeric layer contains substantially no polyetheramide having substantially no ester linkages.
2. The balloon of claim 1 wherein the  
10 polyesteretheramide copolymer comprises a block copolymer.
3. The balloon of claim 1 wherein the polyesteretheramide copolymer comprises a random copolymer.
- 15 4. The balloon of claim 1 wherein the polyesteretheramide copolymer has a hardness of from about 45 Shore D to about 78 Shore D.
5. The balloon of claim 4 wherein the polyesteretheramide copolymer has a hardness of from  
20 about 55 Shore D to about 75 Shore D.
6. The balloon of claim 5 wherein the polyesteretheramide copolymer has a hardness of from about 63 to about 72 Shore D.
7. The balloon of claim 6 wherein the  
25 polyesteretheramide copolymer has a hardness selected from about 63 Shore D, about 70 Shore D, and about 72 Shore D.
8. The balloon of claim 1 wherein the single polymeric layer comprises at least about 2 weight percent  
30 polyamide.

9. The balloon of claim 8 wherein the polyamide is selected from the group consisting of nylon 12, nylon 11, nylon 6, nylon 6/6, nylon 4/6, and combinations thereof.

10. The balloon of claim 9 comprising from about 20 to about 80 weight percent nylon 12 and about 20 to about 80 weight percent polyesteretheramide copolymer.

11. The balloon of claim 10 comprising about 60 weight percent nylon 12 and about 40 weight percent polyesteretheramide copolymer.

12. The balloon of claim 9 comprising from about 25 to about 80 weight percent nylon 4/6 and about 20 to about 75 weight percent polyesteretheramide copolymer.

13. The balloon of claim 12 comprising about 65 weight percent nylon 4/6 and about 35 weight percent polyesteretheramide copolymer.

14. The balloon of claim 1 wherein the single polymeric layer further comprises at least about 2 weight percent of a polymer selected from polyester copolymer, polyurethane copolymer, polyethylene, and combinations thereof.

15. The balloon of claim 1 wherein the polymeric layer comprises at least about 40 weight percent polyesteretheramide copolymer.

16. The balloon of claim 15 wherein the polymeric layer comprises at least about 80 weight percent polyesteretheramide copolymer.

17. A balloon for an angioplasty device having a single polymeric layer consisting essentially of a polyesteretheramide copolymer.

18. The balloon of claim 17 wherein the polyesteretheramide copolymer comprises a block copolymer.

19. The balloon of claim 17 wherein the  
5 polyesteretheramide copolymer has a hardness of from about 45 Shore D to about 78 Shore D.

20. The balloon of claim 19 wherein the polyesteretheramide copolymer has a hardness of from about 55 Shore D to about 75  
10 Shore D.

21. The balloon of claim 20 wherein the polyesteretheramide copolymer has a hardness of from about 63 to about 72 Shore D.

22. The balloon of claim 21 wherein the  
15 polyesteretheramide copolymer has a hardness selected from about 63 Shore D, about 70 Shore D, and about 72 Shore D.

23. The balloon of claim 17 consisting of a polyesteretheramide copolymer.

20 24. A balloon for an angioplasty device having a single polymeric layer comprising (a) at least 91 weight percent polyesteretheramide copolymer, (b) from 0 to 9 weight percent polyamide, and (c) from 0 to 9 weight percent of  
25 a polymer other than polyesteretheramide and polyamide.

25. The balloon of claim 24 comprising at least about 95 weight percent polyesteretheramide copolymer.

FIG. 1

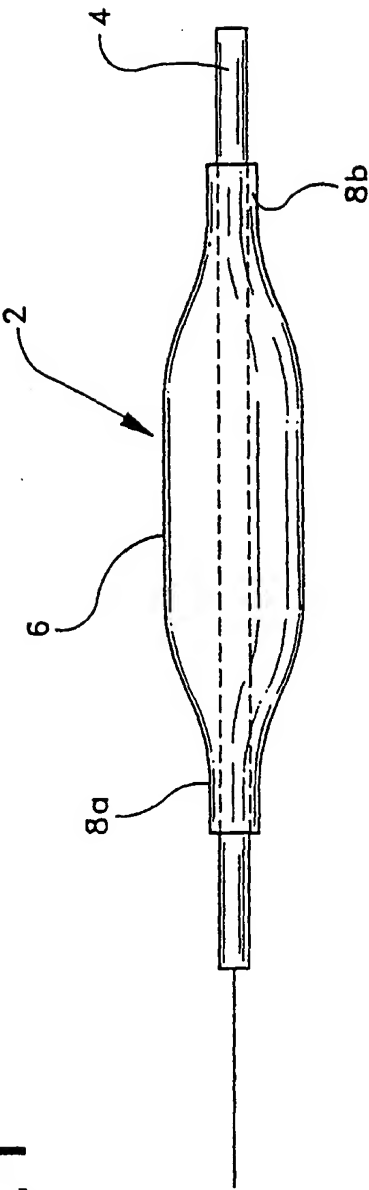
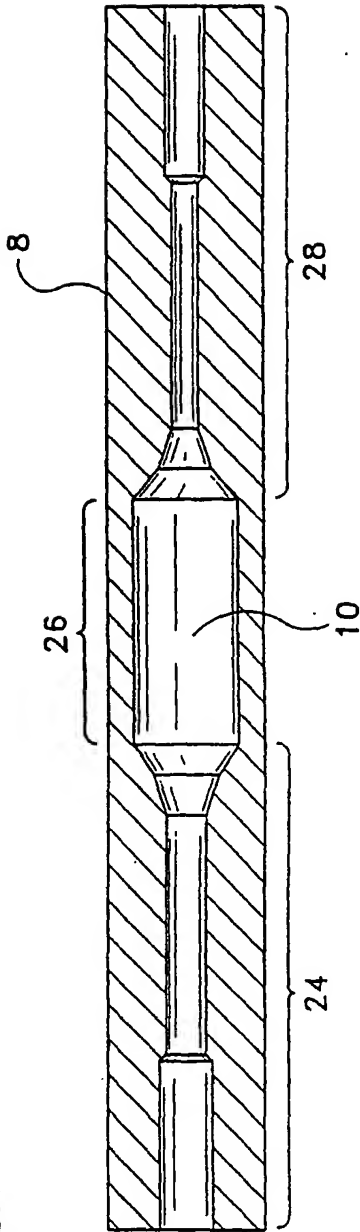
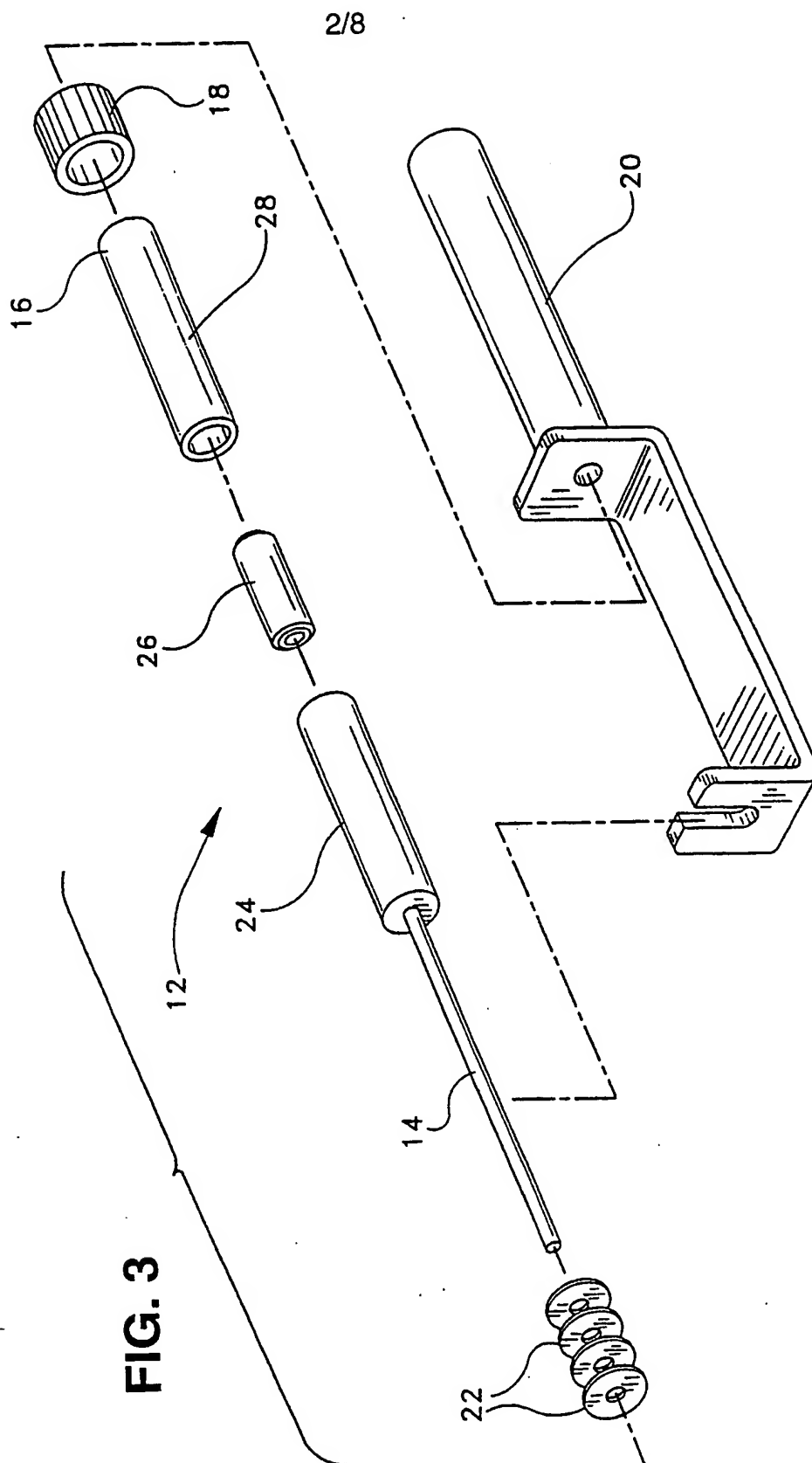
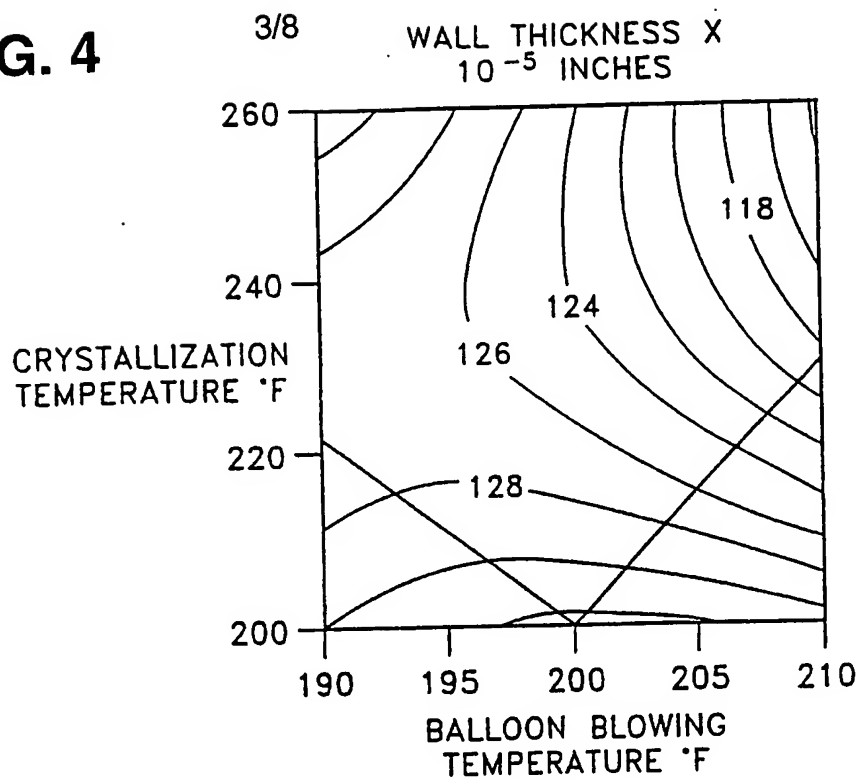
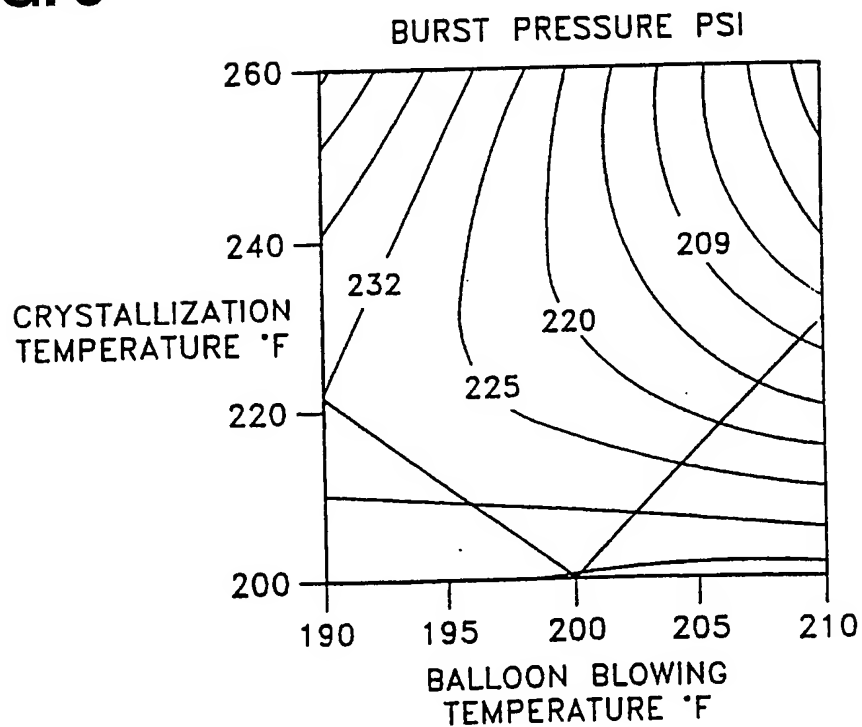


FIG. 2



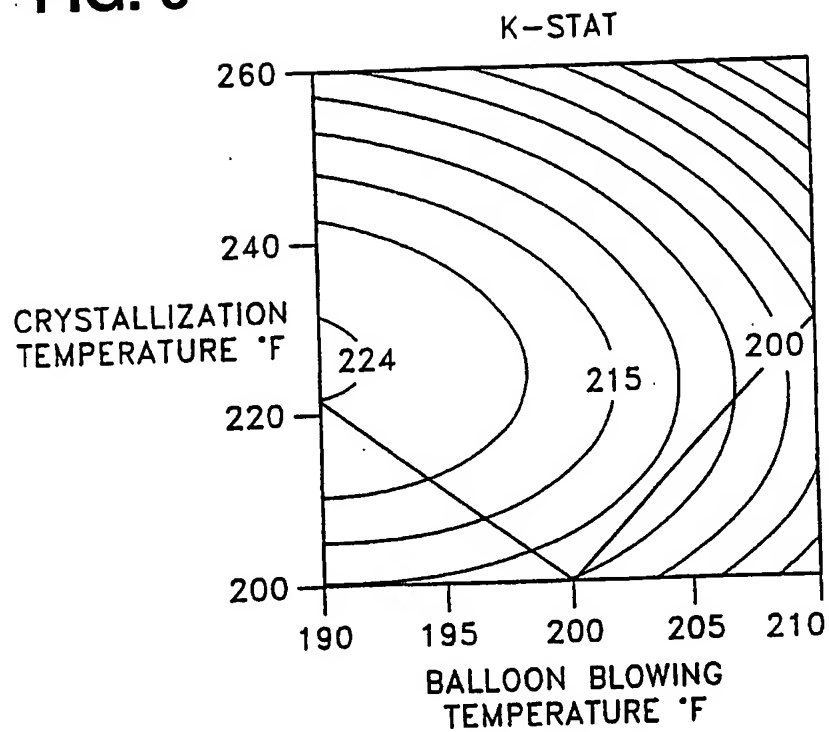
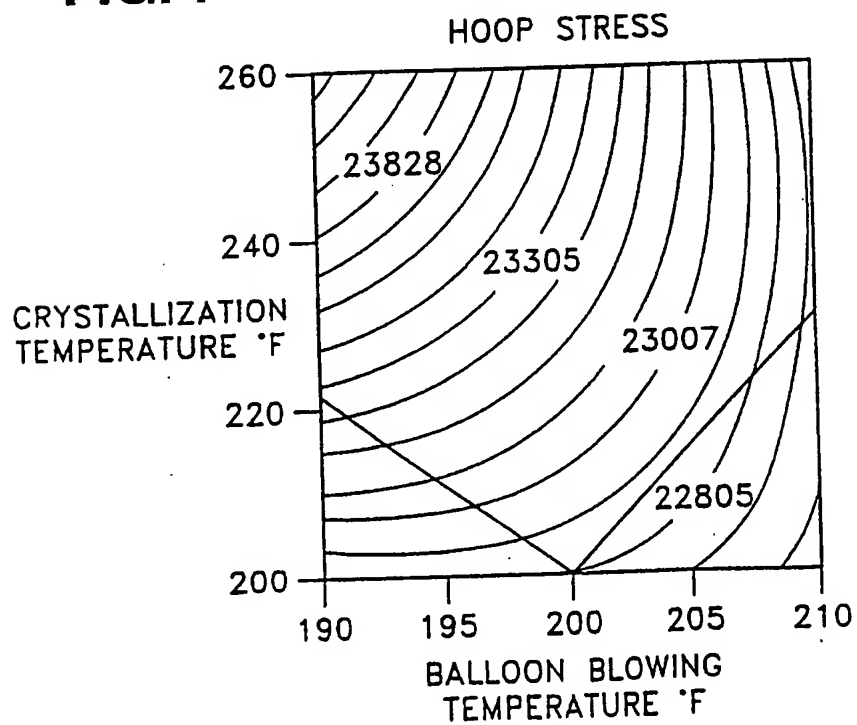


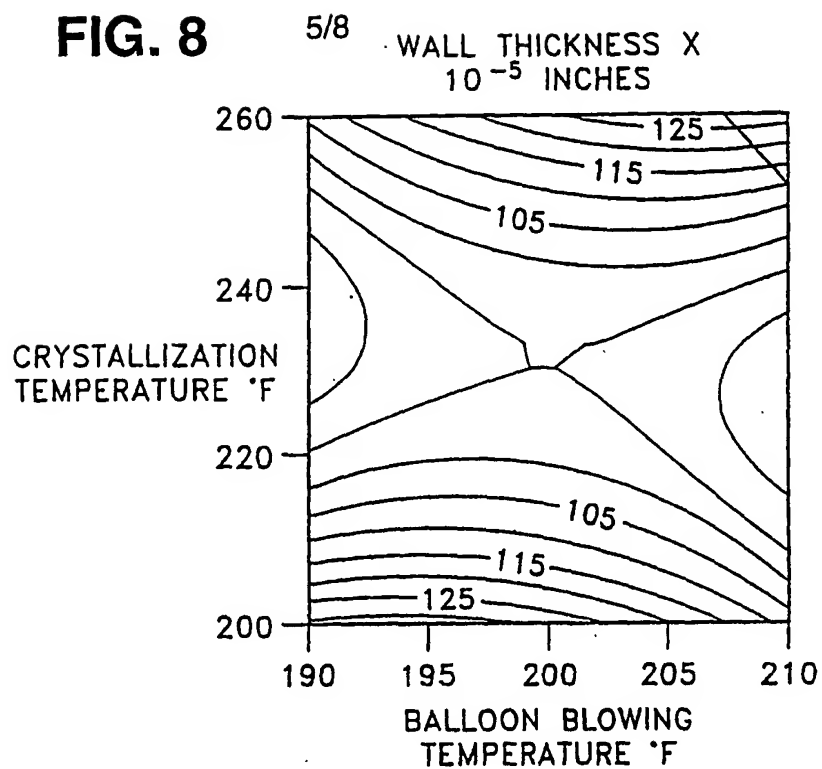
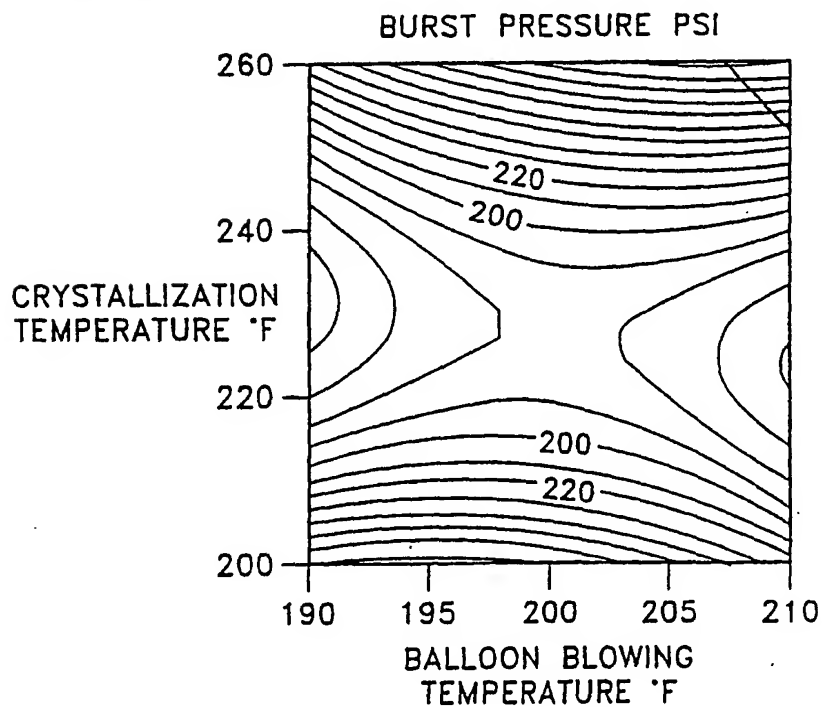
**FIG. 4****FIG. 5**



**FIG. 6**

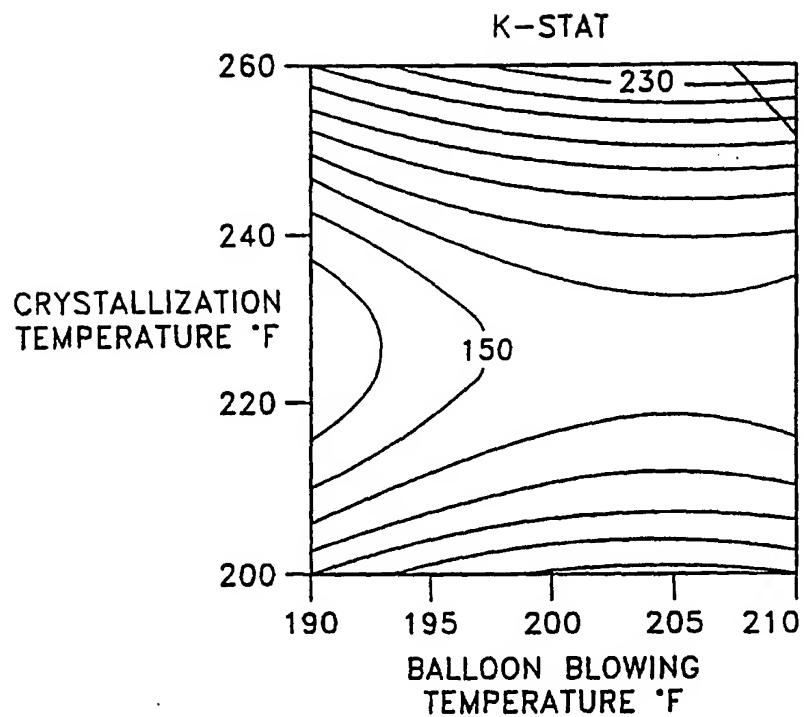
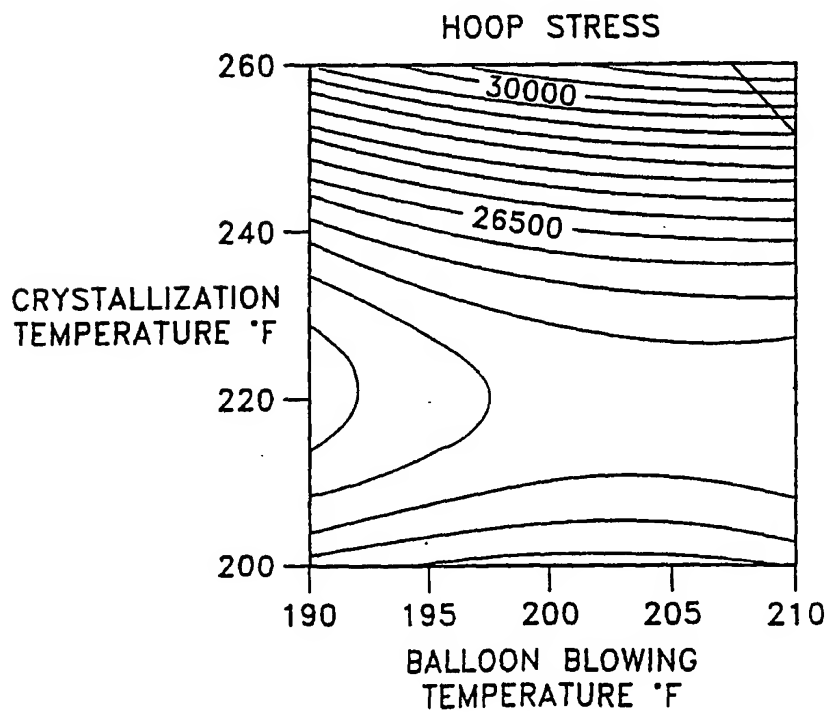
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**FIG. 7**

**FIG. 8****FIG. 9**

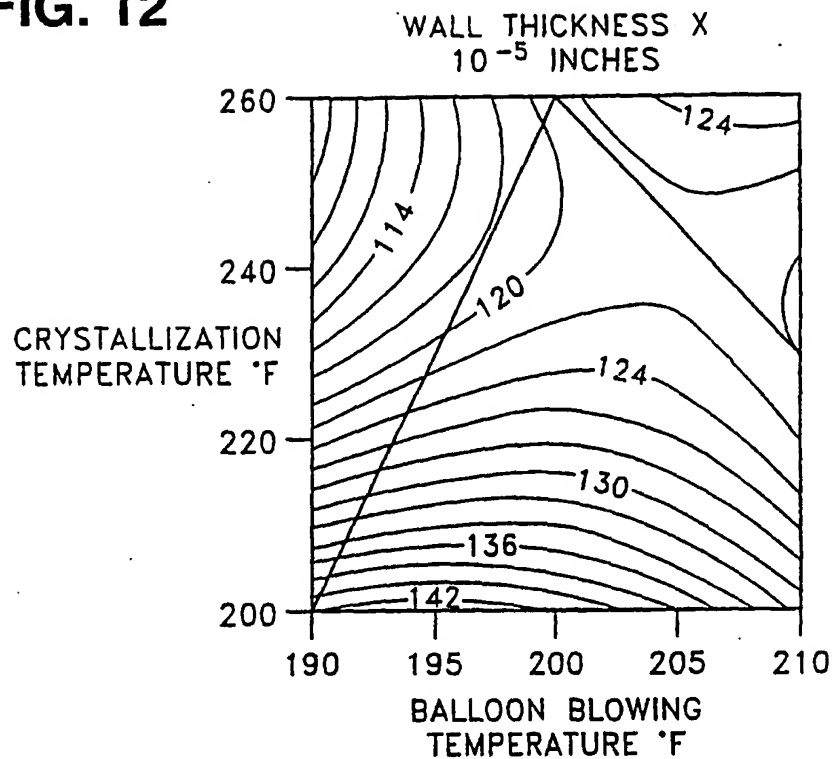
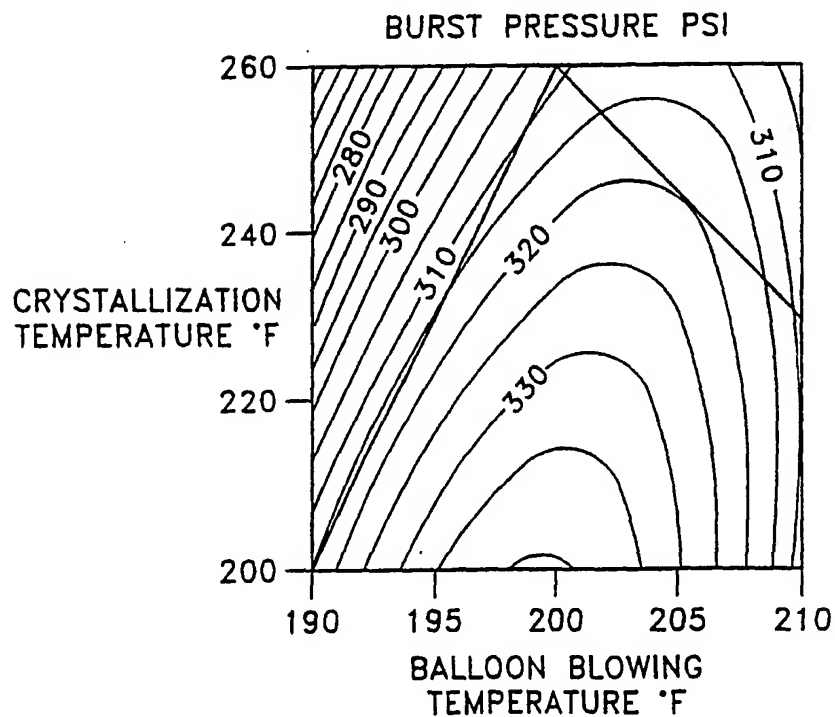
**FIG. 10**

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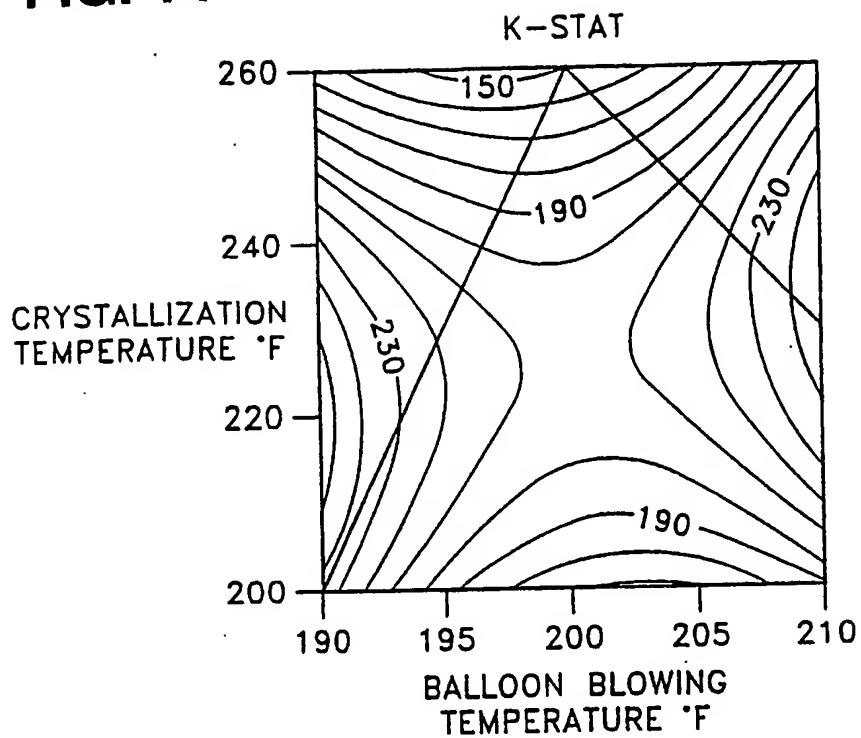
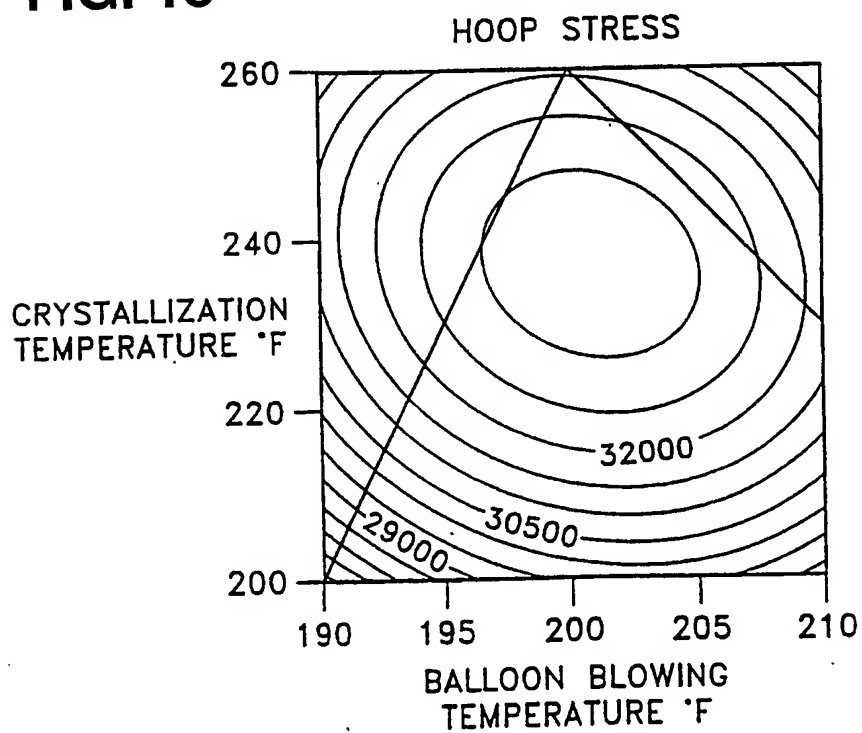
**FIG. 11**

**FIG. 12**

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**FIG. 13**

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**FIG. 14****FIG. 15**

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 96/00291

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61L29/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|------------|--|-----------------------|
| P,X        | WO,A,95 23619 (SCIMED LIFE SYSTEMS) 8<br>September 1995<br>see page 5, line 2 - page 6, line 24<br>see claims 1-4; examples 1-9,11,13<br>--- | 1,2,4-7,<br>15-25     |
| P,X        | EP,A,0 697 219 (ADVANCED CARDIOVASCULAR<br>SYSTEMS) 21 February 1996<br>see page 5, line 15 - line 16; claim 3<br>---                        | 1                     |
| X          | EP,A,0 537 069 (TERUMO) 14 April 1993<br>cited in the application<br>see claims 1,6,7<br>---   | 1,8                   |
| A          | FR,A,2 651 681 (MEDICORP RESEARCH ) 15<br>March 1991<br>see claims 1,3<br>---  | 1                     |
|            | ---<br>-/--  |                       |

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

10 October 1996

Date of mailing of the international search report

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| A          | EP,A,0 117 093 (MALLINCKRODT) 29 August 1984<br>see claims 1-9<br>---                | 1                     |
| A          | WO,A,84 01513 (HARDCASTLE D.) 26 April 1984<br>see claims 3,4<br>-----               | 1                     |

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Information on patent family members

International Application No

PCT/IB 96/00291

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
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